DIRECT-TO-CONSUMER ADVERTISING
OF PRESCRIPTION DRUGS:
MEASURES OF EFFECTIVENESS

DISSE aggregation

Presented in Partial Fulfillment of the Requirements for
the Degree Doctor of Philosophy in the Graduate
School of The Ohio State University

By

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* * * * *

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The objective of this study was to determine if Direct-to-Consumer Advertising (DTCA) was effective in changing attitudes and health behaviors of patients and to determine the effectiveness of DTCA for prescription drug products. Based on Ajzen's Theory of Planned Behavior, this study measured attitudes, subjective norms, perceived behavioral control, behavioral intent, recall of the ad, and actual health behaviors related to BPH assessing if intent leads to actual behavior in a field setting with actual ads. This was accomplished through a post-test only with control group experimental design. The 1093 participants were randomly assigned to one of three groups: product specific ad group, disease specific institutional ad group, and control group. Two self administered mailed questionnaires yielded 296 usable responses for a response rate of 27%.
Respondents in the product specific ad group had a statistically significant higher percentage of respondents recall hearing about Hytrin® and recall seeing an ad for Hytrin® when compared with the other two groups. Multiple regression and correlation analysis showed that patient subjective norms and perceived behavioral control were statistically significant contributors to the total variance explained in affecting patient behavioral intentions regarding DTCA, attitudes, however, were not. The models also showed that variation in the level of effort require of the patient regarding behavioral intentions may affect the amount of variance explained by the model and that behavioral intentions are not always good predictors of actual behaviors. Risk information retention was also assessed.

There was no statistically significant difference among the three groups regarding the correct answering of any of the risk information questions. However, analysis of the data by whether the respondent indicated they had seen an ad for the product or had used the product in the past yielded different results. These results showed that having seen an
ad for the product in the past does increases risk information retention. However, past experience in taking the product provides an even greater degree of retention of risk information, but may also provide a false sense of knowledge regarding some types of risk information.
Dedicated to my mother and father,
(Jan and Donna Sullivan), my fiancée,
(Amy Newman), and my brother, (Gerald Sullivan)
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5) Sullivan, Donald "Mobile Counterattack" (A case study outlining the marketing strategy of Tylenol in the NSAID market), Marketing Management, 1994, Harcourt Brace pps 259-260.


Books


FIELDS OF STUDY

Major Field: Pharmacy
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CHAPTER 1

INTRODUCTION TO THE STUDY

BACKGROUND

In the past, the physician has been the focus of attention for the pharmaceutical industry's advertising and promotional efforts. Also, the physician has been the primary decision maker regarding drug therapy selection. Activities aimed at physicians such as personal sales calls, direct mail, company sponsored symposia, exhibits at health professional conferences, and advertising in professional journals have been the mainstays of prescription drug promotion in the past (Tucker and Smith, 1987). To maximize the effectiveness of these types of promotion, in depth research is conducted by market researchers to learn more about physician prescribing patterns, practice profiles, physician likes and dislikes, and the probability of product use (McRoberts, 1988). However, the days of the physician
as the sole decision maker in drug therapy have disappeared. An increasing amount of input regarding drug therapy selection involves those who pay the bill; the consumer and the third party payer.

Consumers are beginning to take a more active role in their own health care (Schumer, 1987). Consumers expect health care providers to allow more direct involvement in their health care decision making. The traditional role of the physician prescribing a drug and the patient having the prescription dispensed by a pharmacist is rapidly disappearing. Because some consumers continue to pay for pharmaceuticals out-of-pocket, determinations about potential risks and benefits of prescription products are made by these consumers.

To capitalize on the social momentum toward informed consumption and the changing role of the health care decision maker, pharmaceutical manufacturers have begun to explore new and innovative marketing alternatives for prescription drugs (Anon, 1993). Direct-to-consumer advertising (DTCA) is one of these alternatives.

DTCA is defined as any paid promotion material of pharmaceutical treatments, either product specific or disease specific, that is consumer directed (Smeeding, 1990). Based on the content and use of DTCA in the past, the goals of the pharmaceutical manufacturer utilizing this
medium are to increase awareness and create positive attitudes towards the product advertised which will lead to the consumer asking the physician to prescribe the product. The final outcome is increased sales of the advertised product.

Understanding the process leading to the actual behavior of product purchase and advertising effectiveness is commonly measured using consumer behavior models. Some of these models are the Elaboration Likelihood Model, Theory of Reasoned Action, Health Belief Model, and Theory of Planned Behavior (Moorman and Matulich, 1993; Petty and Cacioppo, 1981; Engel, Blackwell, and Miniard, 1990). The researcher felt that some measure of control by the patient over the behavior of interest needed to included in this study. Ajzen’s Theory of Planned Behavior was chosen because of the inclusion of the perceived behavioral control component, in addition to attitudes and subjective norms, which the researcher felt was important based on the patient not having control over the final behavior. The model, overall, was used to gain a better understanding of the effectiveness of DTCA.

Pharmaceutical manufacturers provide DTCA for several reasons, including rising generic substitution, increased competition, decreasing brand loyalty, increased receptiveness of physicians to patients' requests, increased
patient involvement in their health care, and inadequacy in existing channels of communication (Perri and Dickson, 1988). DTCA is viewed as a new avenue to increase awareness of these products in light of decreased use of drug sampling and a greater awareness of quality of life issues (Smeeding, 1990). The apparent goals of DTCA are to increase patient involvement, increase product and disease awareness, and to facilitate communication between the physician and the patient in the decision making process of prescription drug therapy. DTCA allows the consumer to evaluate alternatives and options before the medication decision is made by the physician (Smeeding, 1990).

Several advantages of DTCA for the consumer have been presented (Ruby and Montagne, 1991). These include:

1) increased patient awareness of new therapies,

2) more informed consumers who make better use of their medications, therefore decreasing the costs of noncompliance and possibly the need for further care,

3) increased consumer demand for drug information,

4) increased ability of consumers to take care of themselves and cooperate with the physician,

5) increased active, rather than passive, contribution of the patient to his or her own health care, and

6) decreased prevalence of quackery and use of ineffective products.
DTCA not only benefits the consumer but also the manufacturer. Some of the benefits for the pharmaceutical manufacturer are: (Ruby and Montagne, 1991)

1) accelerated rate of acceptance and use of new medical advances,

2) decreased acceptance of the physician's advice regarding optimal treatments or drugs, and

3) improved company and industry image, achieved by making patients their allies, possibly leading to the development of more positive attitudes towards the manufacturers as a team player in health care delivery.

There is no doubt that DTCA has several potential advantages for both the consumer and the manufacturer, but there is a large void to be filled regarding whether DTCA is effective or not. Determinations regarding effectiveness of DTCA must be made before these potential advantages can truly be realized.
NEED FOR THE RESEARCH

Pharmaceutical companies expect that DTCA will lead to more rapid diffusion and adoption of drug innovations, more rapid market penetration, and eventually increased market share (Doyle, 1994). The goals of DTCA are clear, but measuring its effectiveness is not.

In a previous study, focus groups were conducted with five research and development based manufacturers regarding their use of DTCA as a marketing strategy. These manufacturers were asked, "How will the results of DTCA be evaluated?" All respondents indicated that measuring effectiveness was a major hurdle (Smeeding, 1990). When questioned directly about effectiveness measures, all respondents skirted the issue (Smeeding, 1990). This leaves the question of effectiveness unanswered. Manufacturers are most interested in how many more prescriptions DTCA will generate above and beyond what would normally be generated by promotion to only health care professionals. Policy makers, however, are mostly interested in how consumers assimilate and process the information presented in DTCA.

In the past, DTCA has targeted primarily those medications for medical problems which consumers can easily diagnose themselves such as those for seasonal allergies, hair-loss, and motion sickness. Advertisements for products that treat serious medical conditions whose diagnosis may be
complex were the exception. This is beginning to change. Now, products are being advertised to consumers for serious medical conditions such as benign prostatic hyperplasia (BPH), epilepsy, hypertension, hyperlipidemia, and hormone replacement therapy with potentially serious consequences.

In the spring of 1994, Wallace Laboratories began advertising to consumers Felbatol\textsuperscript{R}, (felbamate), a new drug for epilepsy. These advertisements appeared in popular consumer magazines such as \textit{People Magazine}. The advertisements described the drug as "the first epilepsy medication in 15 years". The advertisements also asked the patient to "tear it out" of the magazine and take the advertisement to their physician asking if Felbatol\textsuperscript{R} could be appropriate for them or someone they cared about. In the summer of 1994, as a direct result of taking Felbatol\textsuperscript{R}, ten patients died from aplastic anemia and ten cases of acute liver failure occurred in which four patients died and one required a liver transplant. The Food and Drug Administration (FDA) therefore recommended that the drug remain available only for patients with severe epilepsy for whom the drug's benefits outweigh the risks. This example illustrates that prescription drugs for serious medical conditions are now being advertised to consumers with sometimes critical consequences.
Past research has allowed only broad postulation of the advantages of DTCA and its effectiveness is an even greater area for question. Functional research available for an actual prescription drug product in a real market environment is scarce (Ruby and Montagne, 1991). Information about the effectiveness of DTCA must be well understood by pharmaceutical manufacturers if they wish to improve patient outcomes and avoid costly mistakes. Therefore, research is needed on DTCA to achieve a balance among understandable and objective patient information, the product details, and the manufacturer's marketing goals.

Authors of two General Accounting Office (GAO) Reports entitled *Little Is Known About the Effects of Direct-to-Consumer Advertising* (1991a) and *Prescription Drugs: Selected Direct-to-Consumer Advertising Studies Have Methodological Flaws* (1991b), concluded that available research does not provide an adequate basis for determining the effects, or likely effects, of DTCA. The majority of research has focused on the acceptance and attitudes of DTCA by consumers and health care professionals. These studies are problematic in that all were conducted on small populations with poor methodological designs (GAO, 1991b). No credible studies were found that permit conclusions to be drawn about the extent to which consumers and physicians support DTCA or about the potential for affecting attitudes
and changing health-related behaviors with DTCA. The GAO requested that methodologically rigorous and systematic studies need to be conducted. The GAO further recommended that, until such time as sound methodological studies are conducted on large populations, the FDA cannot, and should not, make broad policy decisions regarding the appropriate use of DTCA. Until such time, the government is limited in making public policy decisions regarding DTCA regulation, and the practice of case-by-case determinations of appropriateness will continue.

The significance of the GAO findings were made evident to the researcher after discussions with Dr. Nancy Ostrove, Director of DTCA for the FDA\(^1\). She informed the researcher that the FDA is making its decisions regarding DTCA on a case-by-case basis through pre-release clearance. This means the FDA is arbitrarily deciding the appropriateness of individual ads using the subjective criteria of Dr. Ostrove. Since Dr. Ostrove had been recently appointed to this position, the criteria used in the past to determine

\(^1\) Based on a conversation with Dr. Ostrove on June 9, 1994.
appropriateness may change based on her own subjective interpretation. The FDA realizes the importance of developing specific criteria for all DTCA. The FDA has several ideas regarding the type of research that needs to be conducted in order to make broader policy decisions regarding DTCA. However, the FDA lacks the time, money, and personnel with which to conduct these studies, thus the burden falls on academic researchers to provide this research in an unbiased fashion. Therefore, until academic researchers provide methodologically rigorous empirical research regarding DTCA use by consumers and its effectiveness, the FDA is limited in making policy decisions regarding DTCA regulation and will continue its present course of pre-release clearance on a case-by-case basis. This study attempts to provide the FDA with some of the empirical evidence needed to make uniform policy decisions regarding DTCA effectiveness.

The majority of the past research on DTCA has been focused in two areas: assessment of the overall general attitudes of consumers and health care providers towards DTCA, and evaluation of the presentation of risk information on consumer attitudes (GAO 1991a and 1991b). From the data generated in these two areas, poorly drawn conclusions about the effectiveness of DTCA have been made. Some conclusions varied among studies and others were completely
unsubstantiated (GAO, 1991b). Research regarding the phrasing of risk information in DTCA makes an important contribution to the knowledge base, but conclusions about effectiveness from these findings represent a weak link (GAO, 1991b).

SIGNIFICANCE OF THE STUDY

A significant consideration regarding DTCA is the ability of health advertising to influence an individual's behavior. It is possible that advertisements for prescription drugs may in fact serve as an educational intervention. Advertising of prescription drug products may be an important medium to motivate consumers to make behavioral changes that may improve their health. These prescription drug advertisements may be viewed more as educational by consumers than promotional in nature. If so, the information contained in these ads may cause the consumer to incorporate good and/or bad health related attitudes and behavior changes based on the information presented.

The FDA believes that disease specific institutional advertising (i.e. advertising that does not list specific products but rather focuses on overall disease states) is good for patients (Kessler and Pines, 1990). This type of
DTCA promotes awareness of various disease states and motivates consumers to seek treatment (Kessler and Pines, 1990). This is more of a hypothesis than a conclusion by the FDA. Reliable past research on the effectiveness of disease specific institutional advertising was not found. This study assessed whether a disease specific institutional advertisement leads to patients seeking treatment.

Pharmaceutical manufacturers, insurance companies, and employers paying their employees health care costs, may find that the right types of DTCA may be an effective weapon for changing consumer's health attitudes and behaviors. This may promote a cooperative effort between the pharmaceutical industry, insurance companies, and employers to maximize patients' health status while at the same time decreasing health care costs. The patient stands to gain when pharmaceutical manufacturers, insurance companies, and employers work together to improve health outcomes.

DTCA also fosters communication between patients and health care providers who then can play an important role in health behavior modification. DTCA may be a cost effective medium through which attitudes about adverse health behaviors can be changed. In the age of cost containment, all feasible alternatives for impacting health behaviors should be investigated. An example of this is the use of DTCA for changing health behaviors in the treatment of
Benign Prostatic Hyperplasia (BPH). The next section will provide an overview of BPH.

**Benign Prostatic Hyperplasia (BPH)**

Benign Prostatic Hyperplasia (BPH) is a serious health problem for men over the age of 50. The pathological prevalence of BPH increases progressively with age (Nyberg, 1992). It is believed that 50% of all men over the age of 50 exhibit some histological evidence of BPH and by age 85 this percentage rises to 90% (Nyberg, 1992). It is estimated that one out of every four men will require treatment for the relief of the symptoms of BPH by age 80 (Nyberg, 1992). There are currently three treatment options for BPH (Jonler, Riehman, and Bruskewitz, 1994):

1) watchful waiting,
2) pharmacological intervention, and
3) surgery.

Until the actual approval of drugs to treat the symptoms of BPH, surgery was the only treatment option. Transurethral resection of the prostate (TURP) is the surgical procedure used. In 1988, 400,000 TURP surgeries were performed in the U.S. and comprised more than 24% of urologists’ workload and 38% of all major surgeries performed by urologists (Jonler, Riehman, and Bruskewitz,
TURP surgery is the second most common procedure performed in the Medicare population, and the resulting cost is estimated to exceed $5 billion dollars per year (Nyberg, 1992). Therefore, drug therapy represents a more cost effective and less invasive treatment option for BPH. There are currently three pharmaceuticals approved for the treatment of BPH, Hytrin® (terazosin), Cardura® (doxazosin) and Proscar® (finastride).

PURPOSE OF THE STUDY

The purpose of this study was to determine if DTCA was effective in changing attitudes and health behaviors of patients and determined the effectiveness of DTCA for prescription drug products. This study measured attitudes, subjective norms, perceived behavioral control, behavioral intent, recall of the ad, risk information retention of the consumers exposed to the DTCA, and concluded with follow-up mailed surveys of health behaviors related to BPH assessing if intent leads to actual behavior in a field setting with actual ads. This was accomplished through an experimental design using a product specific advertisement and a disease specific institutional advertisement as interventions.
DEFINITION OF TERMS

The definition of the independent and dependent variables is discussed briefly in this section. A more thorough discussion is presented in Chapter 3 under the section entitled Definition and Measurement of Variables. The definition of effectiveness, however, will be discussed in some detail here.

Before effectiveness can be defined, the difference between effectiveness and efficacy must be discussed. In measuring efficacy, the underlying question of interest to the researcher is: Can the intervention work (Sackett, 1980)? Studies measuring efficacy are conducted under ideal conditions and settings and involve excluding potential subjects who appear uncooperative, uninterested, and/or unwilling to comply (Sackett, 1980).

In studies measuring effectiveness, the underlying question of interest to the researcher is: Does the intervention work (Sackett, 1980)? Studies measuring effectiveness must include all who might benefit from a particular intervention regardless of whether they will comply or not (Sackett, 1980). These types of studies are most often conducted in “real world” settings. Therefore the goal of this study was to measure effectiveness of DTCA, not efficacy.
Effectiveness of DTCA can be viewed as a multi-dimensional outcome. The final measure of effectiveness for DTCA is the patient actually taking the prescription product for which they have seen an advertisement. There are, however, several levels or proxy measures of effectiveness depending on how the researcher or manufacturer defines effectiveness of the advertising campaign.

The first level of effectiveness of DTCA is, does the consumer recall seeing an ad for the product advertised. This represents effectiveness at its most basic level. If patients recall seeing an ad for a specific prescription product and the goal of the advertising campaign is only to increase awareness, the ad should be deemed effective.

The second level of effectiveness may be whether or not the patient talks to his doctor about the advertised product. Again, this may be the goal of the researcher or manufacturer for the advertising campaign. The next levels of effectiveness may not only be the ability of the advertisement to convince the patient to speak with their physician about the product, but also to ask for a prescription for the product, and eventually convince the physician to write a prescription for that product. This is different than the previous level of effectiveness. In this measure of effectiveness, the ad must convince the patient to not only mention the product to the physician, but also
help give the patient confidence, the ability, or perceived control to convince the physician to write for that particular product.

The final level of effectiveness is does the patient actually get the prescription filled and comply with therapy. The ad may effective in every step up to this point, but still fail in this final step of convincing the patient to comply with treatment. For this study, our final measure of effectiveness was did the patient actually get a prescription filled for the product advertised for those who received a product specific ad, and did the patient obtain a prostate exam for those who received a disease specific institutional ad. This was the level of effectiveness of interest to the researcher. Other proxy or intermediate measures of effectiveness measured in the study were ad recall, risk retention, and effect on influencing attitudes, subjective norms, perceived behavioral control and behavioral intent.

There were five independent variables included in the study model. The first three were attitude measures. Attitudes were defined in this study as the degree to which the consumer has a favorable or unfavorable evaluation or appraisal of a product or given behavior (Ajzen, 1991). There are three attitudes measured in this study: 1) attitude toward DTCA, 2) attitude toward the product
advertised, and 3) attitude toward asking the physician for a prescription for a given product.

Subjective norms and perceived behavioral control of the consumer were the other two independent variables in the study models. Subjective norms are defined as the perceived social pressure to perform or not to perform a given behavior (Ried and Christensen, 1988). Perceived behavioral control is defined as the perceived ease or difficulty of performing a given behavior (Ajzen, 1991).

Finally, behavioral intent and actual behavior were measured in the study. Behavioral intent is defined as the consumer's predisposition or probability of reacting a certain way when presented with an opportunity to perform a specific behavior (Ajzen, 1991). The measurement of behavioral intent is dependent on the behavioral situation being researched. Behavior is defined by the researcher as did the patient exhibit the behavior, action, or final outcome as defined by the goal of the intervention. For a more complete discussion of the dependent and independent variables, refer to Chapter 2, the section entitled Development Of The Model Used For This Study and Chapter 3, the section entitled Definition and Measurement of Variables.
RESEARCH QUESTIONS AND HYPOTHESES

This study addressed the following research questions:

1) What is the effect of a product specific advertisement, or disease specific institutional advertisement on a consumer's attitude towards DTCA, attitude toward the product, and attitude toward asking the physician for a prescription for a specific drug product?

H 1.1: There is a difference in the consumer's attitude toward DTCA among the three treatment groups (product specific advertisement group, disease specific institutional advertisement, and the control group).

H 1.2: There is a difference in the consumer's attitude toward the product, Hytrin®, among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).
H 1.3: There is a difference in the consumer’s attitude toward asking the physician for a prescription for a specific product among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).

2) What is the effect of a product specific advertisement, or disease specific institutional advertisement on a consumer’s subjective norms, perceived behavioral control, behavioral intent, and actual behavior?

H 2.1: There is a difference in the consumer’s subjective norms among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).

H 2.2: There is a difference in the consumer’s perceived behavioral control among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).
H 2.3: There is a difference in the consumer's behavioral intent to ask the physician for a prostate exam among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).

H 2.4 There is a difference in the consumer’s actual behavior of obtaining a prostate exam among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).

H 2.5 There is a difference in the consumer's behavioral intent in asking for a prescription for Hytrin® if a prostate exam shows the patient's prostate was enlarged among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).

H 2.6 There is a difference in the consumer’s actual behavior in obtaining a prescription for Hytrin® among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).
3) Are there relationships or inter-relationships between attitude towards DTCA, attitude toward the product, attitude toward asking the physician for a prescription for a specific drug product, a consumer's subjective norms, and perceived behavioral control?

H 3.1: The are relationships between the independent variables in the study model.

4) Does the data set fit the proposed study model using multiple regression testing and correlational analysis?

H 4.1: The amount of variance explained by the study models is statistically significant.

5) Do consumers retain risk information from advertisements for prescription drug products?

H 5.1: There is a difference in the retention of risk information among the three treatment groups (product specific advertisement group, disease specific institutional advertisement, and the control group).
ASSUMPTIONS

It is assumed that the sampling frame for this study will be current and accurate. It is also assumed that the respondents possess the proper information and ability to answer the questionnaire. It is further assumed that the respondents will answer the questions truthfully and not based on socially desirable responses. Finally, it is assumed that the respondents will open the piece of mail containing the ad and read the ad.

LIMITATIONS

This study explored the attitude towards DTCA, attitude towards asking the physician for a prescription drug product, and attitude towards the prescription drug advertised, the role of the subjective norms of the patient, behavioral intent to ask the physician for a prostate exam, behavioral intent to ask the physician for a prescription for Hytrin®, the actual behavior of obtaining a prostate exam, and the actual behavior of purchasing a prescription for Hytrin® by consumers. Only those males between the ages of 60 and 75, who have been identified by the mailing list pool of AmericaList Inc. and who reside in Ohio were included in the study. Therefore the conclusions of this study are limited to that of the study group. Any

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generalizations to other groups are only appropriate to the extent that the group is represented by the respondents.

Also, the determinations made by this study about the effect of DTCA on patient's attitudes, subjective norms, behavioral intent, and actual behavioral hold true only for the product class of pharmaceuticals used to treat BPH. Any other generalizations to other individual products or product classes are limited only to the extent that the individuals targeted for that DTCA are similar to the respondents in this study.
ORGANIZATION OF THE DISSERTATION

The dissertation consists of five chapters, appendices, and a selected list of references. The organization of these chapters is described below.

Chapter I contains background information on DTCA, statement of the problem, significance of the study, purpose of the study, assumptions, limitations, and an outline for organization of the study.

Chapter II contains a review of relevant literature including advertising and promotional theory, history of DTCA, regulation of DTCA, past research on DTCA, past research on Benign Prostatic Hyperplasia (BPH), and evolution and development of the Theory of Planned Behavior.

Chapter III describes the methods used in the design of the study. It includes descriptions of sample size calculations, development of research questions and hypotheses, questionnaire design, data collection, and data analysis techniques used for the research questions and study hypotheses.

Chapter IV contains results of the study. A description of reliability, validity, the demographics of the sample, and the results of each test and analysis for the study hypotheses are included.
Chapter V summarizes the findings of the study. Major conclusions of the study are described along with their future implications.
CHAPTER 2

REVIEW OF LITERATURE

Chapter II contains a review of relevant literature including advertising theory, history of DTCA, regulation of prescription drug advertising, past research on DTCA, a review of BPH, and the development of the model used for this study.

ADVERTISING THEORY

Kotler (1988) illustrated why organizations need to promote their products in his definition of the sales concept: "The sales concept is a management orientation that assumes that consumers will either not buy or not buy enough of the organization's products unless the organization makes a substantial effort to stimulate their interest in its products". Promotion and advertising are used to stimulate consumer’s interest through the development of product awareness and changes in consumer attitudes (Dickson, 1994).
According to the *Dictionary of Marketing Terms*, promotion is defined as, "Any identifiable effort on the part of the seller to persuade buyers to accept the seller's information and store it in a retrievable form" (Bennett, 1988). The general subject of promotion can be divided into two categories, personal selling and nonpersonal selling. While personal selling is a feasible alternative for promoting prescription products to physicians, it is not feasible for promoting prescription products to consumers. It is not cost effective for a pharmaceutical sales representative to segment and visit individual consumers. This leaves nonpersonal selling as the only available alternative for promoting prescription products directly to consumers. Nonpersonal selling includes advertising, sales promotion, and publicity. Only advertising was evaluated in this study.

Advertising attempts to promote a seller's product by informing, persuading, and/or reminding the consumer of that product. From a management viewpoint, advertising is a strategic device for gaining or maintaining a competitive advantage in the marketplace (Peter and Donnelly, 1991). Traditionally, advertising has been defined as any paid form of nonpersonal presentation of ideas, goods, or services by an identified sponsor (Bennett, 1988). The ultimate goal of advertising is to increase sales and revenue.
The actual effects and sales impact of advertising are hard to establish outside of an experimental situation in which everything extraneous is held constant (Lilien, Kotler, and Moorthy, 1992). Marketers use several techniques to measure effectiveness of advertising. There are three kinds of effectiveness evaluations that can be made regarding advertisements (Guiltinan, 1991). These are procedures for evaluating specific advertisements, procedures for evaluating specific advertising objectives, and procedures for evaluating motivations impact (Guiltinan, 1991). Some of the procedures for each of the three effectiveness evaluations are provided below.

**Evaluating Specific Advertisements**

1) **Recognition tests**: These are estimates of the percentage of people claiming to recognize an ad when it is shown to them.

2) **Recall tests**: These are estimates of the percentage of people who recall seeing an ad and its contents.

3) **Opinion tests**: Potential audience members are asked to rank alternative advertisements on certain characteristics such as most interesting, most believable, best liked, etc.
4) Theater tests: An audience is asked for brand preferences before and after an ad is shown in the context of a television show.

**Evaluating Specific Advertising Objectives**

1) Awareness: Potential buyers are asked to indicate brands that come to mind in a product category, or a message used in an ad campaign is given and buyers are asked to identify the brand that was advertised using that message.

2) Attitude: Potential buyers are asked to rate competing or individual brands on determinant attributes, benefits, and/or characterizations using rating scales.

**Evaluating Motivational Impact**

1) Intentions: Potential buyers are asked to indicate the likelihood they will buy a brand (on a scale such as definitely will not to definitely will).

2) Market test: Sales changes in different markets are monitored to compare effects of different messages and/or budget levels.

These procedures for measuring effectiveness of advertising for consumer products can be applied to measuring the effects of health-related advertisements such
as DTCA as well as health behaviors. Instead of measuring attitudes toward the brand or intentions to buy a brand, attitudes and intentions can be measured as they relate to particular health behaviors.

Traditionally, the pharmaceutical industry has adopted a "push" strategy in promoting its prescription drug products. With this type of strategy, the company promotes its products to the physician. The physician then writes prescriptions for the product which are then purchased by the consumer. In effect, the company is "pushing" the product through the system by focusing its promotion on the physician and not the end consumer, the patient.

DTCA in effect seeks to stimulate demand at the other end of the distribution channel, the consumer. When the promotion of a product is directed toward the consumer, a "pull" strategy is being used. The pharmaceutical manufacturer attempts to increase sales by "pulling" the product through the distribution system. This is accomplished by directing the promotion of a product at the end user. The pharmaceutical company hopes that the consumer will form a positive attitude towards the product and ask the physician to write a prescription for it.
HISTORY OF DIRECT-TO-CONSUMER ADVERTISING

The beginning of Direct-to-Consumer Advertising (DTCA) could be considered an accident. In 1978, Syntex Inc., a British pharmaceutical company, introduced its new anti-inflammatory compound Naprosyn® to treat the pain associated with arthritis. Without Syntex’s involvement, the risks and benefits of the drug became a topic of discussion on broadcasted talk shows. Syntex Inc. soon realized that this brief, but intensive, exposure to the public had accelerated the drug's use among physicians. This effectively reduced the length of the introductory stage of the product life cycle for this drug (Feisullin and Sause, 1991).

The first use of DTCA in the U.S. occurred in the early 1980's. Pfizer Inc. began a public relations campaign called "Partners in Healthcare". The goal of the campaign was to increase consumer awareness of undiagnosed diseases such as diabetes, angina, arthritis, and hypertension. The advertisements did not mention any specific product names, but prominently mentioned the company name Pfizer Inc.

These types of non-product specific advertisements are referred to as "disease specific institutional advertisements". Disease specific institutional advertisements are designed to increase patient awareness of undiagnosed disease states and urge the patient to seek treatment. It is hoped that this increased awareness will
result in decreased patient morbidity and mortality. The problem is pharmaceutical manufacturers only use these advertisements in selective situations. A pharmaceutical manufacturer will usually use an institutional advertisement when it has the only product available to treat a specific disease state or is the market leader. Under these circumstances, the manufacturer has the most to gain by increasing awareness of previously undiagnosed patients that treatments are available for their medical problem or condition.

When Pfizer Inc. first began using disease specific institutional advertisements, it had brand name products for each of the disease states it advertised. The company hoped to expand the market for its products by alerting undiagnosed patients of these disease states. By placing the company name in the advertisement, Pfizer Inc. was banking on physicians linking a brand name product to the company. This is only effective if the patient mentions the company name or brings the ad to the physician's office. Pfizer Inc. also knew that by expanding the market, sales could increase.

Pfizer Inc. had a significant market share in each of the disease categories it advertised. Therefore Pfizer knew as the market expanded to include previously undiagnosed patients, it would capture the largest increase in sales if
current market share percentages remained stable within therapeutic categories. This type of strategy works only if a company is the market leader in a disease category. If there are competing products on the market, there is a risk of providing free advertising for competitors. Other companies, such as Merck & Co. and Boots Pharmaceuticals Inc., began to move into more product specific DTCA. Merck & Co. began advertising its pneumonia vaccine, Pneumovax®, in 1981, and in 1983 Boots Pharmaceuticals Inc. began advertising its product, Rufen® (an anti-inflammatory agent), directly to consumers.

Merck & Co. conducted its DTCA campaign through print media, such as The Reader's Digest, which specifically mentioned the product name, Pneumovax®. It is not known whether it was Merck's reputation with the FDA or the fact that pneumonia among the elderly was a very serious problem which caused the FDA to react so positively. The FDA did publicly state that the Pneumovax Program exemplified the benefits of DTCA to the public and the industry (Smeeding, 1990). Merck & Co. viewed DTCA of this product as essential because healthy, elderly consumers would not normally see a physician as long as they remained healthy.

In 1983, Boots Pharmaceuticals Inc. was the first company to use DTCA through television and the print media for a brand name product which was generically equivalent to

By 1983, Boots Pharmaceuticals Inc. had failed to gain significant market share from marketing the product to physicians and therefore began to advertise Rufen® to consumers. At the time, the company chose DTCA for several reasons (Smith, 1991):

1) the approaching patent expiration of Rufen® in 1985,
2) a sales force of only 110 Boots sales representatives in U.S. compared to 5,164 total who were detailing other nonsteroidal anti-inflammatory drugs (NSAIDs),
3) the unknown status of the company in the U.S. and
4) the need to convince physicians and pharmacists that Boots Pharmaceuticals Inc. was both patent holder and developer of ibuprofen.

Boots used print and television media to advertise to consumers that Rufen®, a brand name product, was the same as Motrin® but less costly.
The first television commercial aired on May 19, 1983. The next day, Boots Pharmaceutical Inc. received a regulatory letter from the FDA demanding withdrawal of the advertisement by noon on May 23rd for violation of agency regulations. On the morning of May 23rd, John Bryer, Boots' President, and FDA Commissioner Hayes appeared on the Today Show. That afternoon, the FDA held their first consumer exchange meeting discussing DTCA.

Boots voluntarily withdrew the commercial and sent a rebuttal letter to the FDA addressing the allegations. The FDA then approved an alternative commercial on May 24th. Newspaper advertisements later followed after revisions were made which complied with all the points raised in the regulatory letter.

The revised advertisements aired in the Tampa, Florida area for six weeks. As a result, consumer awareness doubled and patient requests for the drug were reported by 29% of the physicians and 62% of the pharmacists surveyed in the Tampa area (Smeeding, 1990). The campaign was then expanded nationally. Even during the 1983-1985 moratorium on DTCA containing product name by the FDA, Boots Pharmaceuticals Inc. changed the ads slightly and continued to run the ads in the print media. Part of the Rufen® campaign also included a rebate coupon to support continued use.

Eventually Boots withdrew its advertising campaign
citing that DTCA was very expensive and its market share had not increased significantly. However, it was realized that increasing exposure does increase awareness. But also, increasing awareness alone does not directly produce increases in prescription sales. Boots had still failed to convince the physicians and pharmacists, even through consumer pressure, to change from Motrin\textsuperscript{R} to Rufen\textsuperscript{R}.

Even during the moratorium on DTCA, pharmaceutical manufacturers such as Syntex Inc. and Merrell Dow Pharmaceuticals Inc. continued to advertise prescription products to consumers without mentioning the product name. After the moratorium was lifted in 1985, a resurgence of DTCA was evident. Advertisements related to pharmaceuticals for not only acute, but also chronic conditions were now beginning to emerge. Pharmaceuticals for chronic conditions such as diabetes, arthritis, ulcers, high cholesterol, and high blood pressure were being advertised to consumers.

In 1981, only one company was using DTCA, but by the end of 1989, 21 companies had used DTCA for over 30 different products (Masson, 1991). Expenditures for DTCA rose from approximately $46.6 million in 1990 to over $162.5 million in 1993 and are still escalating upward (Miller, 1994). In the first six months of 1994, over $125 million had been spent by pharmaceutical manufacturers on DTCA.
(Miller, 1994). The question now became, “Would regulation keep pace with the explosive growth of DTCA?”

REGULATION OF PRESCRIPTION DRUG ADVERTISING

History of Drug Promotion Law

The first federal regulation regarding the advertising and promotion of prescription drugs was passed in 1848 (Smeedding, 1990). This federal regulation required only a listing of ingredients of imported drugs. As more and more pharmaceutical manufacturers started to emerge in the early 1900's, competition and promotion of brand name products began to increase. With this increase in promotion and competition, the amount of false or misleading claims regarding brand name products also increased. This was one of the factors that prompted the passage of the Federal Food, Drug, and Cosmetic Act of 1938.

Originally, the Federal Trade Commission (FTC) regulated prescription drug advertising and promotional activities. The Federal Food, Drug and Cosmetic Act of 1938 granted the FDA jurisdiction over all labeling for both prescription and non-prescription drugs (Kessler and Pines, 1990). However in 1962, the Kefauver-Harris Amendments
granted regulation of non-prescription drug advertising to the FTC.

The Federal Food, Drug and Cosmetic Act of 1938 is the regulation that currently grants the FDA its authority to regulate the advertising and promotion of prescription drugs. The FDA can regulate only those prescription drug promotional (promotion as defined by the FDA includes advertising and promotion) activities that fall within the legal definition of advertising and/or labeling (Kessler and Pines, 1990). The FDA has self-defined its authority in these areas to include almost anything issued by, or sponsored by, a pharmaceutical manufacturer, repacker, or distributor. The only aspect the FDA does not have the authority to regulate is the spoken word of the drug salesperson (Smeeding, 1990). This is protected by the First Amendment, Freedom of Speech.

The FDC Act specifically states that drug labeling may not be false or misleading in any way or fail to reveal any material fact (Kessler and Pines, 1990). However, the Act does not specifically define what is considered advertising. Therefore, the FDA generally views anything, other than product labeling, that promotes a drug product and is sponsored by a manufacturer, distributor, or repacker as advertising (Kessler and Pines, 1990). This includes print and media advertisements. In this sense, the FDA has
extended its authority from the Act to include any false or misleading statements in prescription drug advertisements that is not considered "labeling".

The FDC Act also defines "labeling" as any written, printed, or graphic material upon or accompanying the drug (Adams, 1989). "Labeling" is different from the term "label" which is limited to information on the immediate container of the prescription drug product. The FDA interprets labeling very broadly. Promotional material need not be physically present with the product, only supplement or explain it (Kessler and Pines, 1990). This means that calendars, trinkets, direct mail pieces, detailing pieces, reprints of scientific articles, books used for promotion purposes (Physicians' Desk Reference), and exhibits are considered labeling.

An essential element in the definition of labeling is that the material must be sponsored by the drug's manufacturer, distributor, or repacker (Adams, 1989) An individual with no ties to a company may say anything about a drug product. In this instance, it is neither labeling nor advertising. Also, in the past, specific information asked for by a physician has not been generally considered labeling (Kessler and Pines, 1990).

The FDA has developed specific criteria regarding what information must be included when a promotional activity is
defined as labeling. If the promotional activity is defined as labeling, the material must contain adequate directions for use. The manufacturer, distributor, or repacker, must provide the full product information which has been reviewed by the FDA in the new drug approval process, generally known as the package insert. Any promotional activity defined as labeling must include the entire package insert. Items such as brochures and calendars handed out by the salesperson are considered labeling and must be accompanied by the full package insert.

The requirements for promotional activities defined as advertising are the same, however, with one exception. Instead of providing the entire package insert, advertising may contain a "brief summary" of that information. The pharmacology and dosage sections of the package insert do not have to be included. However, indications for use, warnings, precautions, contraindications, and the drug's adverse event profile must be included. Advertisements in journals and magazines usually only include a brief summary of the package insert.

One of the major concerns of the FDA in the advertising of prescription drugs is the issue of "fair balance" (Kessler and Pines, 1990). In the "fair balance test", the FDA determines whether the information presented in the advertisement provides a balanced account of all relevant
clinical information regarding the drug product. The risks and benefits of the drug must be weighted equally. Providing only the brief summary does not fulfill the fair balance requirement.

There is one class of advertisements that is exempt from the fair balance requirements. This class is referred to as reminder advertising. Reminder advertisements can contain only the drug's name, price, dosage form and/or package type. Any mention in the advertisement of the drug's use, effectiveness, and safety, including visual and graphic cues of these parameters, triggers the fair balance and brief summary requirements (Kessler and Pines, 1990). Reminder advertising can only be used to illustrate the availability of the drug on the market.

Regulation of Direct-to-Consumer Advertising

Problems exist with the regulation of DTCA today because the regulations governing prescription drug advertising were written in 1962 when prescription drug advertising was directed to health professionals only. Prior to 1983, the FDA regulated DTCA in the same manner in which it regulated prescription drug advertising to health professionals. DTCA also had to comply with the brief summary and fair balance requirements.
In 1983, the FDA requested a voluntary moratorium on DTCA. The goal of the moratorium was to allow the FDA to determine if existing regulations regarding prescription drug advertising were sufficient to properly regulate DTCA. During this moratorium, much discussion regarding the regulation of DTCA took place, including a symposium in 1984. Shortly after this symposium, FDA Commissioner Hayes retired and the FDA did not publish any new regulations on DTCA. In 1985 under new FDA Commissioner Frank Young, the FDA removed its moratorium citing that current regulations were sufficient to regulate DTCA.

The FDA currently regulates DTCA under a "pre-clearance" system. Based on past experience, the FDA now offers pharmaceutical manufacturers specific guidance on the "dos and don’ts" of DTCA (Scheman, 1993). Manufacturers using DTCA are strongly encouraged to submit advertisements to the FDA for comments before release. The advertisements must meet the same requirements as those directed towards health care professionals. This includes fair balance and brief summary requirements if the advertisement mentions an indication with a product name. Any advertisement carrying only price information or a product name with no mention of indication, safety, or efficacy is considered reminder advertising and is exempted from the brief summary requirement (Smeeding, 1990).
In 1994, the FDA issued a statement informing manufacturers to "be aware" that in certain jurisdictions, certain products can be prescribed by nurse practitioners, optometrists, pharmacists, and physician assistants (Dickinson, 1994). In locations where this is the case, manufacturers may wish to communicate that a prescription for an advertised product may be obtained from any health care professional authorized to prescribe a given product (Dickinson, 1994).

The approval or disapproval of an advertisement is based on the broad interpretation of the 1962 regulations by the Division of Drug Marketing, Advertising, and Communication of the FDA. If the FDA decides a DTCA does not meet current guidelines, a letter is sent to the company requesting corrective action. This has been successful in more than 99% of the cases, due to pharmaceutical manufacturers unwillingness to challenge the FDA possibly impeding future approvals (Smeeding, 1990).

**Past Research on Direct-to-Consumer Advertising**

Past research has shown that consumers want to participate in decisions regarding their own medical care. (McRoberts, 1988). The Proprietary Association conducted a study which revealed that consumers handled 91% of all
medical problems surveyed without the help of a medical professional (McRoberts, 1988). More specifically, 37% of medical problems were tolerated, 35% were treated with OTC products, 14% were treated with home remedies, 11% were treated with prescription products in the home, and only 9% were treated with the assistance of a medical professional (McRoberts, 1988). Also, a Prevention Magazine study found that 50% of adults reported that they had changed their health behaviors because of information they had read (McRoberts, 1988). This suggests two things. First, consumers want to become active participants in their own health care. Second, consumers are seeking health information on their own from non-traditional sources, such as magazines, television, and newspapers (Morris, 1984).

Much of the past research on DTCA has focused on two areas. The first area is an assessment of the overall general attitudes of consumers and health care providers towards DTCA. The second area includes evaluations of the presentation of risk information on consumer attitudes. From the data generated in these two areas, poorly drawn conclusions about the effectiveness of DTCA have been made (GAO Reports, 1991a and 1991b). These conclusions sometimes varied between studies and others were completely unsubstantiated. There is no doubt that the phrasing of risk information in DTCA makes an important contribution,
but conclusions from this research base do not prove or disprove effectiveness.

Previous research on consumer and physician attitudes towards DTCA have utilized very general measures. There has been no reliable data collected regarding the extent to which positive or negative attitudes are formed and the short-term changes in these attitudes. Therefore, effectiveness of DTCA has not been accurately measured by previous research (GAO, 1991b).

The final problem in assessing the effectiveness of DTCA is the use of intermediate outcomes or surrogate measures from consumer behavior models to determine effectiveness. Consumer behavior models, such as the Fishbein Model, state that behavioral intention is a good predictor of actual behavior, but intentions may not be adequate for determining the effectiveness of DTCA. Even if past research had demonstrated that a consumer reportedly would talk to their physician about the medication or condition mentioned in the ad, would he/she follow through and exhibit this behavior? The process to obtain a prescription for a drug product is more complex and involved than purchasing an OTC product. Therefore, the behavioral intention of a patient to speak with his/her doctor about the product may or may not adequately predict the actual behavior to do so. The question is, "In DTCA, does
behavioral intent indicate effectiveness and are there different levels of behavioral intent?" These questions remain unanswered and this study addresses these some of these issues.

**Attitudes Toward Direct-to-Consumer Advertising and Its Use: Physician and Pharmacist Responses**

Physician surveys regarding attitudes toward DTCA using general attitudinal measures were some of the first research conducted on DTCA. This is most likely due to the interest of health care professional organizations in member attitudes toward DTCA (Spiro, 1992). In 1982, the *American Medical Association (AMA) News* and *American Druggist Magazine* jointly conducted a study that found that 64% of pharmacists and 69% of physicians objected to DTCA (Anon, 1982).

In 1984, the AMA conducted a survey of 1,000 of its own members regarding their attitudes towards DTCA. The study found that 84% of the physicians were opposed to drug advertising on television (Freshnock and Shubart, 1984). The main reasons for opposition cited by physicians were lack of public understanding (34%), reduction of physician discretion (17%), and increased pressure on physicians to prescribe drugs (17%) (Freshnock and Shubart, 1984).
These early studies of physician attitudes toward DTCA provide little more than comparison data in trend analysis of attitudes toward DTCA. Their usefulness is limited based on the rapidly changing health care environment and the decreased control of physicians in product selection over the last decade.

In 1992, a research study of physicians conducted by Scott-Levin and Associates, a health care marketing information firm, found that consumer awareness of DTCA is increasing, consumers are becoming more involved in prescription drug decision making, and physicians are becoming more receptive to consumer input (Scott-Levin and Associates, 1992). Specifically the study found that:

1) 84% of physicians who were notified by a patient about a drug will at least consider prescribing it and 16% are very likely to prescribe it,

2) the percentage of physicians who indicated that patients raised the subject of alternative treatments rose from 53% in 1989 to 93% in 1992,

3) the proportion of physicians who indicated that patients had requested a drug by a brand name rose from 45% in 1989 to 88% in 1992,

4) 78% of the physicians indicated that patients discussed symptoms seen in DTCA in 1992 compared to 30% in 1989,
5) 44% of physicians indicated that patients started discussions by bringing in DTCA, compared to 21% in 1989 and,

5) 16% of the physicians surveyed indicated that they would continue with the original planned regimen regardless of patient requests in 1989, compared with only 1% in 1992.

Conversely, the study found that 56% of the physicians surveyed reported opposition to DTCA. So why are physicians so responsive to patient requests stimulated by DTCA? The study found that many physicians believe that patients who get the drug they ask for are more motivated to comply with treatment. Theoretically, if the patient is more compliant with drug therapy, then better health outcomes should be observed. Also, due to competitive factors, physicians are struggling to maintain an adequate patient base. Many physicians struggle between keeping the patient satisfied and their own personal judgment regarding treatment alternatives. Poor reception of consumer suggestions of certain drug therapies may promote physician shopping and erode the patient base (Perri and Dickson, 1987).

The Scott-Levin study, however, had some potential flaws that may affect the generalizability of results. First, the method used to sample the universe of all
physicians should be questioned. The study utilized a random sample from the American Medical Association’s (AMA) physician’s list. Therefore, those physicians who are not AMA members are not represented in the sample. Also, the list only contains physicians with office practices. This would exclude those physicians practicing exclusively in hospital setting such as an emergency room or trauma physician. Also, there may be some other common characteristic of physicians who are not members that the sample does not represent, therefore some groups of physicians may be underrepresented by the sample.

The major problem with the study, however, is its low response rate. The study used a mailed questionnaire for data collection, yielding a response rate of 8.4% in 1992 and 11.0% in 1989 (Scott-Levin and Associates, 1992). There was no attempt to contact non-respondents and no adjustments were made to compensate for non-response bias. Therefore it is very difficult to make generalizations to the population of interest, all physicians, regarding attitudes toward DTCA and its use, based on such a low response rate.

Finally, validity of the research instrument may be questioned. Examination of the research instrument by the GAO indicated that physicians may be indirectly led to the appropriate response by the wording of the questions (GAO,
1991b). This may lead to biased responses from the study sample.

A recently presented study explored the attitudes of pharmacist’s toward DTCA (Duttagupta, Aparasu, Deselle, et al., 1994). The objective was to measure pharmacist’s attitudes toward DTCA in the state of Louisiana. Questionnaires were mailed to 10% of the state’s licensed pharmacists who were randomly selected for inclusion. A response rate was not provided (Duttagupta, Aparasu, Deselle, et al., 1994).

Results showed that 59% of those pharmacists responding did not support DTCA, but 60% of the respondents indicated that they had been asked by consumers about drugs advertised using DTCA. In general, the pharmacists surveyed felt that DTCA would lead to higher prices for prescription drugs. Chi-square analysis illustrated that attitudes toward DTCA were independent of all demographic variables measured. Overall, the study results indicated that pharmacists have some questions about the appropriateness DTCA, but they do recognize it can be useful (Duttagupta, Aparasu, Deselle, et al., 1994).

Their study was exploratory in nature. The conclusions made from the study are only generalizable to the extent that other sub-populations of pharmacists are representative of the study sample. Also, no response rate was provided.
Their study does, however, provide some insight into pharmacist’s attitudes that DTCA can be useful in some circumstances, but not all prescription drug products should be advertised directly to consumers.

**Consumer Attitudes Toward Direct-to-Consumer Advertising**

Attitudes of consumers toward DTCA encompasses the largest part of DTCA research conducted to date. This is most likely due to the ease in data collection of “opinion only”, exploratory research. Much of this research was conducted in the middle 1980’s when DTCA was first introduced and measured consumer attitudes toward DTCA.

The first research into consumer attitudes toward DTCA was conducted by the FDA. The FDA held 50 meetings across the U.S. from April through October of 1983 and obtained the views of 1,200 individuals regarding their attitudes toward DTCA. Overall, 50% of those attending were opposed to all forms of DTCA, 20% were in favor of DTCA, and 30% were in favor only if DTCA was carefully controlled by governmental organizations (Morris, Brinberg, Klimberg, et al, 1986a). However, the sample was biased; 45% of those attending were members of consumer advocacy groups and 29% were affiliated with the government or public health organizations. These
surveys, therefore, did not truly represent the attitudes of the average consumer regarding DTCA.

The next study of consumers’ attitudes towards DTCA was conducted by the Lifetime Cable Network. On Sundays in the mid to late 1980’s, Lifetime Cable Network aired medical programming targeted toward health care professionals. These programs contained advertisements for prescription drugs. Any consumer who had access to cable television could watch this medical programming targeted for health care professionals.

Participants in the study were consumers who viewed Lifetime’s “Physician’s Journal Update”. This program was targeted to health care professionals and contained several advertisements for prescription drugs. Consumers were recruited to participate in the study by calling a toll-free number displayed during the program. Between October and December 1993, 990 consumers responded. Consumer respondents were asked a variety of questions regarding programming and DTCA. The results of survey are as follows (Morris, Brinberg, Klimberg, et al. 1986b):

1) 91% believed that prescription drug advertising would make patients better informed,

2) 95% responded that DTCA would make consumers aware of new therapies,
3) 94% responded that DTCA would be of benefit to the consumer,
4) 32% responded that advertisements would confuse patients, and
5) 32% responded that DTCA could get patients to pressure physicians to prescribe drugs.

Only those viewers who watched the program, “Physicians Journal Update” were studied. These respondents could have been consumers, health care professionals, or consumer advocates. Consumer respondents, if any, may have been more educated, and health conscious than a normal consumer. These viewers may also have been comfortable with DTCA because they had the ability and knowledge base to understand the information provided. Therefore, the generalizability of these results is limited only to those consumers who watched “Physician’s Journal Update”. These consumers are not likely to be representative of the population base of the U.S. Overall, the results of this study are limited in their generalizability due to biased sampling and weak methodologies.

In the summer of 1984, the American Medical Association (AMA) conducted a telephone survey of 1,503 randomly selected adults regarding their attitudes toward the advertising of prescription drugs on television. Two-thirds
of the respondents said they oppose DTCA on television (Freshnock and Shubart, 1984). Those opposing DTCA cited that physicians should be the judge (25%), fear of increased drug abuse (21%), lack of consumer understanding (11%), undermining the patient-physician relationship (7%), misleading the public (5%), and causes higher prices (4%) (Freshnock and Shubart, 1984). Of the 34% who supported DTCA on television, 25% responded that DTCA helps consumers make more informed choices and 24% responded that DTCA has educational value (Freshnock and Shubart, 1984).

In the same year, researchers at the University of Minnesota found vastly different results regarding consumer attitudes toward DTCA. This unpublished study conducted by Leonard Rosenberg and the University of Minnesota College of Pharmacy utilized a mailed questionnaire of 133 randomly selected Minnesota residents. Overall, the Minnesota study found that only 34% objected to DTCA, 37% did not object, and 28% had mixed reactions. Furthermore, the study found that 55% believed DTCA could create a more informed consumer, and 59% responded that it would not damage physician and pharmacist reputations. However, 51% responded that DTCA may lead to drug abuse and that DTCA was dangerous and 67% felt that DTCA would increase self-medication.
The next study regarding consumer attitudes toward DTCA was conducted in 1984-85 by four researchers at the FDA and one academician. (Morris, Brinberg, Klimberg, et al., 1986a and 1986b). The study was conducted in four cities: Buffalo, Cleveland, Houston, and Seattle. Telephone interviews were used to screen potential respondents which were selected through random digit dialing in those cities.

Adult consumers with hypertension or arthritis in the households selected were asked to participate. Those selected were then asked to report to a central facility in their city to view some health information. Each participant was paid $20 for travel expenses and their time. Fifty-two percent (1509) of those agreeing to participate attended a session. The attending respondents were randomly split into two groups. One group was given a magazine with 20 minutes to read through it and the other watched a 17 minute television show. Afterwards, both groups were asked to complete a self-administered questionnaire. The instrument measured attitudes on a 1-5 Likert-type scale with 1 = strongly agree and 5 = strongly disagree.

Embedded within the magazine were two full page advertisements for two fictitious drugs, Artomine for arthritis and Dirovin for hypertension. There were 16 other full page advertisements within the magazine. Within the television program there were two 60-second advertisements
for the same two fictitious drugs. There were no other advertisements in the television program. This may be considered a methodological flaw of the study.

Overall, the study subjects attitudes towards DTCA were positive. Sixty-one percent of the respondents indicated that they would like to see advertisements for prescription drugs and 66% agreed that prescription drug advertisements provide useful information. Also, half of the respondents (50%) believed prescription drug advertisements would benefit consumers and 88% saw the advertisements as stimulating information-seeking from the physician. However, there were some areas of concern to consumers.

Forty-six percent of the respondents believed that DTCA would increase drug costs and 74% agreed that only a doctor could tell if a prescription drug should or should not be used. However, 36% disagreed that only a physician could tell if a DTCA was truthful or not. Also, 58% disagreed that a drug that is advertised to consumers must be safe. Finally, the study demonstrated that consumers are not altogether passive. Fifty-two percent responded they would ask their physician to prescribe a specific drug if they wanted the product.

The study also measured consumer’s attitudes toward the products advertised. This part of the study sought to
determine whether magazine or television advertisements produced more favorable attitudes toward the product, and not whether DTCA overall creates positive attitudes toward the product. The overall attitude toward the product was probably not reported because there was not a control group to use for comparison. Therefore, only comparisons between media types (magazine and television) could be made. This part of the study could have made a significant contribution to the literature regarding effectiveness of DTCA, but instead the researchers were interested more in risk information phrasing and effectiveness of different media types.

The study found that television advertisements produced more positive attitudes toward the product than magazine advertisements. Those consumers who viewed television advertisements were also more likely to ask their doctor about the drug. However, consumers in the magazine group were more concerned about the disease. The television group was also less likely to get upset with their physician if he/she refused to prescribe the medication. The researchers concluded television advertisements are used by consumers as more awareness arousing and magazine advertisements are used by consumers as more explanatory and persuasive.

This study appeared to be methodologically sound with a strong study design and appropriate sampling technique. The
two treatment groups, however, in this study were not equal. The magazine group had 16 other advertisements to compete for the reader’s attention, information processing, and recall ability, while the television program had none. Five of the fourteen items measuring attitude toward DTCA were statistically different between the magazine group and the television group. This could possibly be due to the difference in media used or discrepancy in the number of other advertisements to which the consumer was exposed. The cause of these differences is inconclusive.

This study did, however, compare the overall sample to the 1980 U.S. census data. There were no significant differences in terms of sex, marital status, and race between the sample and census data. The sample was, however, better educated and, as expected, older. The sample respondents were expected to be older because only those individuals with hypertension or arthritis were invited to participate. There are, however, two other judgment call problems besides the inequality of the treatment groups.

First, the study was conducted with fictitious products. “Methodologically sound studies measuring effectiveness need to be conducted on real products in real world settings” (GAO, 1991b). The main point of this statement is that effectiveness research needs to be
conducted on real products in field settings. The setting was artificial, but appropriate due to time and cost constraints the researchers operated under. Research on DTCA should be conducted on real products to provide a sound foundation to support a study’s conclusions.

Second, there was not a control group in the study. The researchers should have used a pre-test or a control group. This would have given the researchers a comparison point as to how exposure to DTCA affects consumer attitudes. From the study as it is presented, effectiveness of DTCA or changes in attitudes of the consumers toward DTCA cannot be concluded. However, the researchers were more interested in providing data on the differences in media selection on attitudes than overall effectiveness and should not be faulted for their intent. The conclusions made based on different media’s effect on attitudes are slightly weak due to the inequality of the two treatment groups. Finally, the study did examine the effect of risk information presentation in DTCA and study will be presented in the subsequent section, Risk Information Research in DTCA.

Perri and Nelson (1987) conducted an exploratory study of consumer attitudes toward DTCA in 1985-86. Data were collected using a convenience sample of consumers at two shopping malls. The sampling technique used quota sampling
to ensure all age groups were represented, obtaining a total of 139 responses.

Each respondent was shown five advertisements, 2 OTC advertisements and 2 prescription drug advertisements. One of the prescription products, Pneumovax\textsuperscript{R}, had been advertised to consumers and the other, Donnatal Extentabs\textsuperscript{R} had not. The Donnatal\textsuperscript{z} advertisement was included as a validity check for false responses. All of the advertisements used were taken from popular consumer magazines except for the Donnatal\textsuperscript{R} advertisement which was taken from a medical journal.

Attitudes were measured based on six items using a 5-point Likert type scale. The questionnaire also used a single item which broadly measured behavior intention. Consumers were asked if they would ask their physician about medications they had seen advertised. Consumers were also were asked to recall if they had seen any of these advertisements before. Data were collected using personal interviews.

Twelve percent of the respondents recognized the Pneumovax\textsuperscript{R} advertisement. Significantly more consumer recognized the advertisements for the OTC products. This is not surprising since the consumer advertising budgets for OTC's are usually significantly larger than those for prescription products advertised directly to consumers.
Only four respondents recognized the advertisement for Donnatal®; the dummy advertisement, of which two of these were health care professionals.

Perri and Nelson made the conclusion that those consumers who had been exposed to the Pneumovax® advertisement in the past were able to recognize it. However, they did admit that aided-recall is not the most rigorous test of recognition. For the analysis of attitude toward DTCA, respondents were divided into two groups, those who recognized the Pneumovax® advertisement and those who did not. This placed 17 participants in the aware group and 122 in the unaware group. The aware group respondents had neutral attitudes towards DTCA and the unaware group had slightly favorable attitudes toward DTCA.

The two groups also were analyzed together as one group. In this combined analysis 82% felt that DTCA would provide information they had a right to know. Ninety-two percent indicated they wanted this type of information, but 88% believed it should come only from their doctor or pharmacist. Finally, 46% felt that prescription drugs for serious illnesses should be advertised directly to consumers and 55% felt that prescription drugs should not be advertised like OTCs are.

The study did attempt to measure behavioral intention. The item used was very broad in its wording. The item
asked, “Would you ask your physician about prescription medications you have seen advertised”. Eighty-three percent of the respondents indicated they probably would ask their physician, 10% were unsure, and 7% would not. This information only allowed the researchers to make very general conclusions about the behavioral intentions of consumers exposed to DTCA. This behavioral intention may be situation specific and may change based on the product advertised and the attitude of the consumers. It would have been helpful if the researchers had analyzed the relationship between attitudes toward DTCA and behavioral intention.

Overall, the study was exploratory in nature and the researchers make this point very clear. Therefore, conclusions regarding consumer attitudes toward DTCA, recall ability, and behavioral intentions are limited.

**Risk Information Research in Direct-to-Consumer Advertising**

A large part of the Morris et al. study (1986a and 1986b), previously discussed, was the determination of the effect of risk information provided in DTCA (see also Brinberg and Morris, 1987). The advertisements for the two fictitious products varied the risk information on: 1)
whether the brief summary was integrated with the promotional message or presented separately (2 levels), 2) the amount of risk information presented (2 levels), and 3) whether general or specific risk information was presented (2 levels). This design, however, did have a control group in which the advertisements the consumers viewed had no risk or precautionary information.

While conducting the study, the researchers noticed that several participants in the magazine groups were ignoring the advertisements in the first two test cities, Buffalo and Houston. Therefore, the researchers made the decision in the third city, Cleveland, to tell the participants to pay attention primarily to the advertisements. In the fourth city, Seattle, participants were told to pay attention only to the ads. This produces artificial study conditions and further biases the results.

The researchers did analyze recall differences between the four cities. Magazine readers in Buffalo and Houston were three times more likely not recall the main point of the advertisement compared to magazine readers in Seattle. As expected, magazine readers in Cleveland, told to pay attention primarily to the advertisements, were twice as likely not to remember the main point of the advertisement compared to the magazine readers in Seattle, who were told
to only pay attention to the ads. This is a limitation of the study.

To measure recall of risk information, a 16 item true-false knowledge test was given. Eight of the 16 items measured promotional aspects of the advertisements and eight items were based on risk disclosure. Based on the analysis by the researchers, the ability to communicate risk information and promotional information from the advertisements were equal indicating that recall of both promotional information and risk information by study participants was equal.

The study results suggested that the media chosen, phrasing of risk information, and the format of the advertisements influenced both recall and description of risk information. However, the researchers do make the point that the artificial nature of the testing circumstances do limit the conclusions of the study. The study specifically found that television advertisements were more effective at conveying risk information than magazine advertisements. Also, the presentation of specific risk information led to a greater recall of risk information. The presentation of general risk information in the advertisements were found to be no more informational than the control group. Finally, the separation of risk information from the advertisement resulted in lower recall
scores than advertisements in which the risk information was integrated within the advertisement. Overall, specific risk information is more informative than general risk information. However, emphasizing risk information in the advertisement may not be more effective than not emphasizing it. This depends on the media used and viewing conditions (Brinberg and Morris, 1987).

Another study by Tucker and Smith (1987) measured the presentation of risk information and its effect on informational value, sense of security, appeal of the advertisement, and clarity of the advertisement. The sample size of 192 was calculated and obtained using a convenience sample of adults at a regional shopping mall over a three day period. Quota sampling was used to ensure equal distribution of respondents based on sex and age.

The study utilized four fictitious advertisements of an influenza virus vaccine, Fluvax. Each of the four advertisements contained the same promotional message, however, each advertisement varied in terms of the phrasing of risk information. There were three advertisements with risk information and one control group. The risk information presented in each of the three advertisements was placed in a box in the lower portion of the advertisement and entitled, “Special Considerations for Those Persons Who Take Fluvax”.

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The first advertisement contained a general warning statement mentioning that all medications have side effects and patients should consult a physician to determine if the vaccine is safe and effective for them. The second advertisement contained information similar to the brief summary format. It contained detailed precautionary information under the subheadings indications, contraindications, warnings, precautions, and adverse reactions. The third advertisement contained the same detailed precautionary information as the second, but was presented in a narrative format without the subheadings. The fourth advertisement contained no risk information. Respondents were given only one advertisement each and then asked to complete a self-administered questionnaire.

The results showed that the advertisement which contained the brief summary information with headings (advertisement 2) was judged to have the higher information value by the respondents. This advertisement was only significantly different in informational value from the advertisement with no risk information. The results of a Scheffe test also indicated that advertisement 1 & 4 (general risk information and no risk information) and advertisements 2 & 3 (brief summary w/headings and narrative brief summary) formed homogenous subsets regarding sense of security presented by the ad. These two subsets were
significantly different in consumer's views of sense of
safety. To the surprise of the researchers, those
advertisements with no risk information or general risk
information were judged as providing more security to the
consumer than those which contained detailed risk
information. The researchers suggested this may be due to
the inability of the respondents to understand and process
the more detailed summaries of risk information.

The study also found that those advertisements that
contained any amount of risk information (advertisements 1,
2, & 3) were found to be more appealing by consumers than
advertisements which did not contain any risk information.
Finally, the study did not find any significant differences
between the advertisements regarding the clarity of the
information presented.

As in the Morris et al. study (1986a and 1986b), the
use of a fictitious product in an artificial setting may
provide less than reliable results with limited
generalizability. The researchers in this study, however,
did use a validated mall intercept data gathering technique.
The researchers sampled only entrances to the mall,
entrances were randomly assigned to intercept time
intervals, and only subjects moving in the main mall area
were used. The researchers believed that these techniques
would result in the reduction of bias in the study (Tucker and Smith, 1987).

Research on Effectiveness of Direct-to-Consumer Advertising

There are only a limited number of studies that have attempted to measure the effectiveness of DTCA. Only two such studies were found by this researcher. A study by Perri and Dickson (1987 & 1988) utilized the same two advertisements for two fictitious products that were used in the Morris et al. study (1986a and 1986b) (previously discussed), Artomine for arthritis and Dirovin a skin patch for hypertension. Each of these advertisements specifically stated that patients should ask their doctors about the medical conditions and the drugs advertised. Two internal medicine physicians, two family practice physicians and 50 patients from each physician were selected (n=200). Patients selected for inclusion in the study were not acutely ill, but were scheduled for periodic rechecks or a physical exam. Not all of the patients included were diagnosed with either arthritis or hypertension.

Advertisements for both products were mailed such that participants would receive the advertisements ten days and three days prior to their physician’s appointment.
Advertisements for both products were included in each mailing with the order of presentation switched each time. The statement, “Important Health Information For You” was printed on the outside of the envelope in boldface print. Patients were observed by their physician during their appointment, and each subject was given a questionnaire by the receptionist to complete at home. Of the 155 patients observed by their physician, 94 returned usable questionnaires.

Patients and physicians both rated the perceived patient involvement in his/her own health care. Interestingly, patient and physician involvement scores were not correlated \( \text{Pearson } r = 0.13, p = 0.10 \). This may imply that patients and physicians may not view patient involvement the same way. However, consumer’s self-report of their health status and the medical condition reported by the physician were moderately correlated \( \text{Pearson } r = 0.432, p < 0.01 \).

Seventy percent of the respondents reported that they had seen a DTCA, but only 11% were able to write the name of at least one of the drugs advertised. Of the 155 patients evaluated by the physicians, 8.4% (13) inquired about at least one of the advertised products. Also, patient involvement in their health care was related to their inquiring about either of the advertised products. The
researchers hypothesized patients scoring high on involvement in their health care would be more likely to inquire about either of the two drugs advertised. This hypothesis was not supported by the study results. The researchers did find, however, that more drug inquiry behavior is found in patients who perceived their overall health status to be lower.

Finally, a Chi-square analysis was conducted to determine if there was a relationship between the incidence of arthritis and hypertension and the patient’s drug inquiry behavior. The analysis showed a significant relationship \[ X^2 = 20.33; p < 0.001; \text{d.f.} = 3 \]. Twenty percent (12 of 66) of the patients who had either arthritis or hypertension solicited drug information from the physician regarding either of the two advertised products. Also, physicians reported that the advertisements had no negative effect on patient-physician relationships, and that patient requests for specific products may have stimulated them to actively search for more information about the drug (Perri and Dickson, 1987, 1988).

This study, like many of the others, was exploratory in nature. One of the problems with the study was that consumers completed the questionnaire at home. Therefore, they may have still had the advertisements and used them when completing the questionnaire, possibly biasing their
responses. Ideally, the researchers should have had the patient complete the questionnaire in the office. Another problem, as with the Morris et al. study (1986a and 1986b) and the Tucker and Smith study (1987), was the use of fictitious products. It extremely hard to draw conclusions based on the responses to fictitious products. This study did, however, use more of a realistic setting in exposing the patients to the advertisements.

Everett (1991) attempted to determine the effectiveness of DTCA using a fictitious product, Predone. Respondents were selected from a five county metropolitan area around Denver, CO. The sample was generated using random digit dialing yielding 238 respondents. Telephone interviews were conducted to obtain the needed data.

Consumers were read this hypothetical situation over the phone:

"Let’s assume you have a sore back, but you haven’t gone to the doctor yet. If you happen to see an ad for Predone, a brand of muscle pain reliever, but you have to get a prescription from you doctor to take...."

The researcher found that approximately 33% would ask their physician to prescribe Predone and only 5% would
change physicians if their request for Predone was not satisfied. The study also showed (Everett, 1991):

1) 66.4% would read the advertisement carefully,

2) 71.6% would tell their doctor they had seen the Predone advertisement,

3) 70.6% would discuss Predone’s effectiveness with their doctor and,

4) 34.7% would ask their doctor to prescribe Predone.

This study used a weak research design and methodology to determine the effectiveness of DTCA. First of all, this is the most artificial of all situations to measure attitudes and behavioral intentions. The patient was not exposed to an advertisement and was asked to visualize this situation over the phone. The reliability and validity of the data collected from this intervention is questionable.

The researcher concluded that, “the potential dangers of DTCA stem from the possibility that audience members will employ irrational or inadequate strategies when processing DTCA information”. The researcher should be cautioned in making this conclusion when the respondents had virtually no information provided to them to process. The researcher
further concludes, "the data suggests that, in general, lay audience members will not tend to approach prescription drug advertising and product selection as a low-involvement trivial task". The researcher did not measure nor manipulated consumer involvement, therefore conclusions such as these should not be made from the data collected.

Much of the past research has focused on attitudes toward DTCA and the phrasing of risk information in DTCA. This research provides insight into overall attitudes toward DTCA of physicians, pharmacists, and patients, but does not directly address the effectiveness issue. The study conducted by Morris, Brinberg, Klimberg, et al, (1986a and 1986b) attempted to address the issue of effectiveness, but fell short due to the artificial setting of the study and use of ads for fictitious products. It did, however, set the stage for field studies on real ads by validating measures for three different attitude constructs. This dissertation study utilizes these measures and applies them to actual ads in a real world setting.

For the current study, the researcher chose advertisements for a prescription drug used to treat Benign
Prostatic Hyperplasia (BPH). DTCA for this class of pharmaceuticals has been used in the past by the pharmaceutical industry. This class of pharmaceuticals was chosen because of the ability of these drugs to improve a patient’s quality of life, and the ease with which the target population can be segmented for intervention. A brief overview of BPH will be presented next.

**BENIGN PROSTATIC HYPERPLASIA (BPH)**

Benign Prostatic Hyperplasia (BPH) is a serious health problem for men over the age of 50. BPH is the most common cause of voiding dysfunction in men (Jonler, Riehman, and Bruskewitz, 1994). The pathological prevalence of BPH increases progressively with age. It is believed that 50% of all men over the age of 50 exhibit some histological evidence of BPH and by age 85 this percentage rises to 90% (Nyberg, 1992). BPH is responsible for 1.7 million physician visits and 482,000 hospitalizations every year (Calciano, Resnick, Schmidt, et al., 1993). It is estimated that one out of every four men will require treatment for the relief of the symptoms of BPH by age 80 (Nyberg, 1992).
The symptoms of BPH are caused by the growth of the prostate gland that occurs with age. This growth “squeezes off” the urethra that passes through the center of the prostate gland. The growth of the prostate gland is facilitated by androgens, testosterone and its more active metabolite dihydroxytestosterone. The prostate gland has the ability to metabolize testosterone into the more active dihydroxytestosterone. A combination androgens and older age leads to the enlargement of the prostate gland known as BPH.

Most men develop a combination of symptoms caused by BPH. These symptoms include; obstruction of urination, hesitancy in starting a urine stream, decreased force of urinary stream, post-void dribbling, frequent urge to urinate, and being awakened during the night to urinate. A recent study has shown that symptoms can interfere with a patient’s activities of daily living (Garraway, 1993). Garraway (1993) found that 51% of the symptomatic BPH patients studied reported disruption of at least one activity of daily living and 20% reported disruption of at least four activities of daily living.

There are currently three treatment options for BPH (Jonler, Riehman, and Bruskewitz, 1994):
1) watchful waiting,
2) pharmacological intervention, and
3) surgery.

Until the development of drugs to treat the symptoms of BPH, surgery was the only treatment option. Transurethral resection of the prostate (TURP), a surgical procedure, is considered still the gold standard of therapy. However, this surgical procedure places a considerable strain on urologists’ time and financial resources of the patient and the health care system. (Banna and Rushdi, 1993). Furthermore, patients with mild to moderate symptoms are not always candidates for TURP surgery (Banna and Rushdi, 1993).

In 1988, 400,000 TURP surgeries were performed in the U.S. TURP surgeries comprised more than 24% of urologists’ workload and 38% of all major surgeries performed by urologists (Jonler, Riehman, and Bruskewitz, 1994). TURP surgery is the second most common procedure performed in the Medicare population, and the resulting cost is estimated to exceed $5 billion dollars per year (Nyberg, 1992). The average TURP surgery without complications costs approximately $12,000 (Calciano, Resnick, Schmidt, et al., 1993). Also, TURP surgery recipients usually require 3 days in the hospital (Jonler, Riehman, and Bruskewitz, 1994). However, there are significant consequences of TURP surgery.

TURP surgery has a mortality rate of approximately 1% and a morbidity rate of 17%. Also, 15% of males who have this surgery are not helped and recurrence of urinary
obstruction can occur in up to 20% of patients. Finally, incontinence and/or impotence may occur in a small number of men who have TURP surgery (Stoner, 1990). Drug therapy, therefore, may represent a more cost effective and less invasive treatment option for BPH.

There are currently three oral drugs approved for the treatment of BPH, Proscar® (Merck & Co.), Hytrin® (Abbott Laboratories), and Cardura® (Roerig, a division of Pfizer Inc.). Proscar® works by inhibiting the enzyme testosterone 5-alpha reductase which converts testosterone to the more potent dihydroxytestosterone. This results in the shrinkage of the prostate. The results of several studies indicate the ability of Proscar® to shrink the prostate occurs in only 9%-28% of patients treated with the drug (Jonler, Riehman, and Bruskewitz, 1994). In some studies of Proscar®, improvement in symptoms was not significantly different from the placebo group and maximum urinary flow rate increased by only 22% (Banna and Rushdi, 1993). Another problem with Proscar® is that it may take up to six months before any improvement is seen. Therefore, past research leaves significant doubts regarding the effectiveness of Proscar®.

The prostate gland contains many alpha receptors that cause constriction of the smooth muscle. It has been estimated that about 40% of the total urethral pressure in
patients with BPH is due to alpha adrenergic tone (Banna and Rushdi, 1993). Therefore resistance of the prostatic urethra may be altered with alpha receptor antagonists. Hytrin and Cardura are the only alpha receptor antagonists approved for the treatment of BPH.

Previous studies have shown that, after as little as four weeks of therapy with Hytrin, most patients observed an increase of 60% in maximum urinary flow rate (Banna and Rushdi, 1993). This compares to 108% increase with TURP surgery. Also, 63% of patients reported a significant improvement in obstructive symptoms and 67% reported a marked improvement in other urinary symptoms (Jonler, Riehman, and Bruskewitz, 1994). Hytrin does have a high incidence of side effects such as dizziness, syncope, orthostatic hypotension, and asthenia (Lepor, Auerbach, Puras-Baez, et al., 1992). However, these side effects are usually not a problem if the drug is taken at bedtime. Therefore, based on the review of literature regarding effectiveness in treating BPH and the fact that Hytrin has been used in DTCA campaigns, it was a logical choice for the study for several reasons.

This study was a field study using real ads targeted directly to the potential end user of the product. Because BPH mainly affects men over the age of 60, the researcher could segment this part of the population from existing
databases. Based on segmentation by age and gender, the research could ensure the ads reached the population they were targeted. Identifying the target population for other product classes of DTCA, such allergy suffers, high cholesterol patients, and hair loss suffers, would have required extremely large sample sizes and initial disease state identification surveys just to segment these special populations. Also, existing databases are not sophisticated enough to contain accurate data regarding health conditions and disease states at the level of the individual consumer. Finally, Cardura® was not chosen because at the time of the study DTCA for this product did not exist.

DEVELOPMENT OF THE MODEL USED FOR THIS STUDY

The last section of this chapter is devoted to a review of the model used for this study. It provides the rational for its selection in the DTCA domain and it traces the development of this model for use in this study.

Original Fishbein Model

The ability to explain human behavior has perplexed social scientists for years. Much of the early research on explaining behavior was done by Fishbein and Ajzen. They developed the expectancy-value model, later to be known as
the Fishbein Model, as a way of explaining and predicting an individual's behavior (Fishbein and Ajzen 1975).

According to the Fishbein Model, attitudes develop reasonably from the beliefs people hold about an object (Fishbein and Ajzen 1975). Individuals form beliefs about an object by associating it with certain attributes. The attributes of a given object are valued either positively or negatively by each individual. The individual also places various levels on importance on each attribute. The value of each attribute to the individual is multiplied by its importance to that individual. The resulting products for each attribute are then summed. This yields an expectancy-value score. An individual's expectancy-value score is directly proportional to an individual's attitude towards that object. Figure 1 illustrates the original Fishbein Model.
\[ \sum (B_i) (E_i) \xrightarrow{} A_o \xrightarrow{} BI \xrightarrow{} B \]

\[ B_i = \text{belief that a product possesses attribute } i. \]
\[ E_i = \text{evaluation of attribute } i \text{ of a product} \]
\[ A_o = \text{attitude toward the product} \]
\[ BI = \text{behavioral intention toward the product} \]
\[ B = \text{behavior exhibited toward the product} \]

**Figure 1: The Original Fishbein Model**

An attitude is defined as a predisposition to respond favorably or unfavorably towards a given object, product or behavior. An individual will remember the attitude towards an object long after the evaluations of the object's attributes (expectancy-value score) are forgotten. Consumers are cognitive misers such that attitudes are formulated toward products as a short-cut instead of remembering and evaluating all of the product's attributes every time a given behavior will be exhibited. Fishbein and Ajzen demonstrated that the higher the expectancy-value score for a given product, the more positive the individual's attitude towards that product is and, the more likely the individual will purchase that product. Therefore, if an individual has a choice between three
products, the one with the more positive attitude should be the one the individual chooses. However, there is a major problem with the application of this model.

Most of the time the researcher cannot be present to observe an individual's actual behavior. Since most of the settings for the testing of this model were artificial, Fishbein and Ajzen developed the construct of behavioral intent as a surrogate outcome measure for behavior. The researchers believed that the strength of this behavioral intention was directly proportional to the probability of the individual exhibiting the actual behavior.

Intentions are assumed to capture the motivational factors that influence a behavior. Intentions are indications of how hard individuals are willing to try, or how much of an effort they are planning to exert, in order to perform the behavior (Ajzen, 1991). In general, the stronger the intention to perform a behavior, the more likely that behavior will be exhibited by an individual.

Originally, this model provided the most promising results for explaining and predicting behavior, but problems arose. In many situations, and for many behaviors, the model was not adequate in predicting and explaining an individual's behavior (Burnkrant and Page, 1988). Many times an individual's expectancy-value score and his/her attitude were directly proportional, but the behavioral
intent was inversely proportional (Sheppard, Hartwick, and Warshaw, 1988).

**Theory of Reasoned Action**

The low explanatory power of the Fishbein Model in many situations perplexed Fishbein and Ajzen (Ajzen and Fishbein, 1980). The researchers felt something else was affecting an individual's behavioral intent. They believed that a social factor may affect behavioral intent or actual behavior; e.g. significant others who are important to the individual may affect an individual's behavioral intent and actual behavior. The researchers also postulated that, depending on the situation, pressure to do what others think is appropriate may sometimes be stronger than the individual's own attitude towards a behavior.

This led to an expansion of the original Fishbein Model by adding another component which may affect an individual's behavioral intent or actual behavior. This component was known as an individual's subjective norm. This new model was known as The Theory of Reasoned Action, also referred to as the Extended Fishbein Model (Ajzen and Fishbein, 1980). Figure 2 illustrates the Theory of Reasoned Action.
\[ \Sigma (B_1) (E_i) \rightarrow A_0 \rightarrow BI \rightarrow B \]

\[ \Sigma (NB_j) (MC_j) \rightarrow SN_j \]

\[ BI = w_1 (SN_j) + w_2 (A_0) \]

\[ B_1 = \text{belief that a product possesses attribute } i. \]

\[ E_i = \text{evaluation of attribute } i \text{ of a product} \]

\[ A_0 = \text{attitude toward the product} \]

\[ NB_j = \text{normative belief of referent group } j \]

\[ MC_j = \text{motivation to comply with referent group } j \]

\[ SN_j = \text{subjective norm of the individual across all } j \]

\[ BI = \text{behavioral intention toward the product} \]

\[ (BI \text{ is the sum of the weights of the subjective norm and the affective attitude}) \]

\[ B = \text{behavior exhibited toward the product} \]

\[ w_1 \text{ & } w_2 = \text{empirically determined weights representing the components' relative influence} \]

**Figure 2: Theory of Reasoned Action**
Normative beliefs ($NB_j$) are defined as the likelihood that an important referent individual(s) or group(s) approve or disapprove of performing a given behavior (Ajzen 1991). The motivation to comply with what each referent group approves or disapproves is the second component of the Theory of Reasoned Action. The strength of each normative belief ($NB_j$) is multiplied by the person's motivation to comply ($MC_j$) with the referent person or group in question. These are summed across all referent persons or groups. The resultant sum is known as the individual's subjective norm ($SN$). This subjective norm is directly proportional to the sum of the resultant products across ($j$) salient referents.

The Theory of Reasoned Action now proposed by Ajzen and Fishbein has two conceptually independent determinants of behavioral intention. The first is the attitude towards the behavior. This refers to the evaluation of the behavior in question which is either favorable or unfavorable. The second determinant is a social factor, the subjective norm. The subjective norm refers to the social pressure to perform or not to perform a given behavior (Ajzen 1991). The individual then places weights on his/her attitude and subjective norms. The sum of the weighted attitude and weighted subjective norm is then directly proportional to behavioral intent. The Theory of Reasoned Action, however,
still did not explain a significant proportion of the variance in certain behavioral situations (Ajzen, 1991).

There was still something missing that possibly could add to the model's explanatory power and help explain a larger proportion of the variance. From previous research, Ajzen realized that the ability for an individual to perform a given behavior is not always under the direct control of the individual (Ajzen, 1991). There are many behavioral situations that an individual may have incomplete volitional control. This led to the development of Ajzen's Theory of Planned Behavior.

**Theory of Planned Behavior**

As in the Theory of Reasoned Action, the central factor in the Theory of Planned Behavior is the individual's behavioral intention. It is important to note that a behavioral intention can find expression in behavior only if the behavior in question is under direct volitional control i.e., if the person can decide at will whether to perform or not perform the behavior (Ajzen 1991). Some behaviors adequately meet this requirement, but most are dependent to some degree on such nonmotivational factors such as availability of requisite opportunities and resources. Some of these resources and opportunities may include time,
money, various skills, and cooperation of others. Therefore, these resources and opportunities must to some extent dictate the likelihood of behavioral achievement. The addition of the variable perceived behavioral control (PBC) measures the degree of control an individual feels he/she has in exhibiting a given behavior.

Perceived behavioral control is defined as a person's perception of the ease or difficulty of performing the behavior of interest. Perceived behavioral control is situation specific. It is not a global control measure based on psychological factors and/or personality traits. It is based on the resources or opportunities available to the individual for a specific behavior. Figure 3 illustrates its role in the theory of planned behavior.
\[ A_0 \]

\[ SN_j \rightarrow BI \rightarrow B \]

\[ PBC \]

\[ A_0 = \text{attitude toward the product} \]

\[ SN_j = \text{subjective norm of the individual} \]

\[ PBC = \text{perceived behavioral control in a given situation.} \]

\[ BI = \text{Behavioral Intention toward the product} \]

\[ B = \text{Behavior exhibited toward the product} \]

**Figure 3: The Theory of Planned Behavior**

The idea that behavioral control may affect intentions as well as actual behavior is not new in theory. The construct of perceived behavioral control was developed from past research (Ajzen, 1991). It is therefore important to compare the construct of perceived behavioral control with other conceptions of control.
One of the most widely known and used constructs of control is Rotter's Perceived Locus of Control (Rotter 1964). Perceived locus of control is a generalized expectancy that remains stable across situations and forms of actions. However, perceived behavioral control can, and usually does, vary across situations and actions. According to locus of control, a person may believe that, in general, his/her outcomes are determined by his/her own behavior (internal locus of control). At the same time, he/she may also believe that his/her chances of becoming president are very slim (low perceived behavioral control), yet his/her chances of becoming a high school teacher are very high (high perceived behavioral control). This illustrates the difference between the two concepts of control.

Another approach to perceived control can be found in Atkinson's Theory of Achievement Motivation (Atkinson 1964). The primary focus of this theory of perceived control is the expectancy of success. This may be viewed as similar to perceived behavioral control in that it refers to a specific behavior and not to a generalized predisposition as in locus of control. However, the expectancy of success is not entirely situation specific. Achievement motivation is defined as a general disposition which the individual carries about him/her from one situation to the next (Atkinson 1964). The general achievement motivation was
assumed to combine multiplicatively with the situational expectancy of success as well as with another situational specific factor, the "incentive value" of success (Atkinson 1964).

Ajzen’s recent view of perceived behavioral control is most similar to the concept of perceived self-efficacy or self-efficacy beliefs (Bandura, 1977 and 1982). The concept of perceived self-efficacy is concerned with the judgments of how well one can execute courses of action required to deal with prospective situations (Bandura, 1982). Much of the knowledge about situational behavioral control comes from the early research of Bandura. His research has shown that a person's behavior is strongly influenced by his/her confidence in his/her ability to perform the behavior.

These self-efficacy beliefs can influence an individual's choice of activities, preparations for a specific activity, effort expended during performance of that activity, as well as attitudes, thought patterns, and emotional reactions. Ajzen’s theory of planned behavior places the construct of self-efficacy belief or perceived behavioral control within a more general framework of the relations among beliefs, attitudes, intentions, and behavior (Ajzen, 1991).
The Study Model

For this study, the Theory of Planned Behavior was chosen to help explain and understand the variance in DTCA effectiveness due to the complexity of the purchase process. The process of purchasing of a prescription drug product by the consumer is complex. A favorable attitude toward a product and pressure from significant referent group(s) probably will not adequately explain the variance in the behavior of obtaining a prescription for a specific product as demonstrated by past research (Ajzen, 1991).

Unlike an over-the-counter product, a patient cannot go directly to the pharmacy and purchase a prescription drug product following exposure to an advertisement. The consumer must expend a considerable amount of effort progressing through a series of steps before finally obtaining the prescription product. The most difficult of these steps may be convincing the physician to write a prescription for a specific product. The amount of perceived behavioral control an individual feels he/she has in convincing the physician to write a prescription for a specific product is very important. This is why a modified Theory of Planned Behavior will be used.

The model constructed for this study to explain the variance and factors in DTCA effectiveness is very similar to Ajzen’s Theory of Planned Behavior. It is similar except
for one modification, the attitude component. Ajzen’s model has a single construct which gives an overall measure of an individual's attitude toward the product. The study model uses three separate attitude constructs of which each independently may have a separate effect on intention and behavior. The three separate attitude components were first postulated by Morris et al. (1986a and 1986b). Their study identified three separate and distinct attitude constructs and was verified through factor analysis. This study will use the same three attitude constructs and items used to measure these constructs as developed by Morris et al. (1986a and 1986b).

The three attitude constructs included in the model are: 1) attitude toward the product, 2) attitude towards DTCA advertising, and 3) attitude towards asking the physician for a prescription for a specific product.

Attitude toward the product comes directly from previous Fishbein and Ajzen models including the Theory of Planned Behavior. Past research indicates that attitude towards the product and intention are directly proportional (Sheppard, Hartwick, and Warshaw, 1988). The higher the attitude score toward a product then the higher the intention to purchase that product.

Morris et al. (1986a and 1986b) measured attitude toward the product advertised in their study, but
comparisons were made in attitudes only between television and magazine ad. There was no control group nor pre-test, so conclusions regarding the ability of the ads to change attitudes was not measured. Our study will measure the actual attitude difference between a control group and a group that received actual ads for the product.

Attitude toward DTCA in general also was believed to be a separate construct for this study based on the research by Morris et al. (1986a and 1986b). This attitude toward DTCA may affect intention in two different ways. First, an individual may have a negative attitude toward advertising prescription products to consumers. This may predispose them to form a negative attitude toward the product advertised because of their negative attitude toward DTCA. The individual therefore will not process the information in the advertisement or this predisposition may cause them to form a negative attitude towards the product regardless of the information contained in the advertisement. This may also present the reverse for positive predisposition towards DTCA.

Second, the individual may process the information contained in the ad and initially form a positive attitude toward the product, but sometime in the near or distant future form a negative attitude towards DTCA in general. The initial positive attitude toward the product may still
be in the individual's memory, but the negative attitude towards DTCA may inhibit or change the individual's intention. As previously discussed, individuals form attitudes about products as cognitive shortcuts. If the researcher were to only measure attitude towards the product, this may be very positive and thus indicate a high degree of intention. But the attitude towards DTCA in general may in fact inhibit this intention.

Based on past research by Morris et al. (1986a and 1986b) toward DTCA in general was included as a separate construct. Even if an individual's attitude toward DTCA may be negative, the positive attitude toward the product may still remain. The individual just recalls he/she has a positive attitude toward a product with no recollection as to how this attitude was formed.

The third construct, attitude towards asking the physician for a prescription for a specific product, was included for the same reason as attitude towards DTCA in general and was based on previous research by Morris et al. (1986a and 1986b). An individual may have a positive attitude towards the product and towards DTCA, but if he/she does not have a positive attitude towards asking the physician for a specific prescription product then behavioral intention is likely to be low. If this third attitude construct is omitted, false predictions about
intentions might be made. It is believed that this third attitude construct may increase the explained variance in intentions and actual behavior.

It must be noted, however, that the study by Morris et al. (1986a and 1986b) did not attempt to combine all three attitude constructs into one model. Attitude toward DTCA was measured to assess overall attitudes toward DTCA. Attitude toward the product and attitude toward asking the physician for a prescription for a specific product was measured to determine differences in effectiveness between magazine and television advertising. The three constructs were not combined into a single model to try to explain the variance in DTCA effectiveness. This was not the purpose of the Morris et al. study (1986a and 1986b), but is the focus of this study. Figure 4 illustrates the final model to be tested.
$A_o$ = attitude toward the product

$A_d$ = attitude toward DTCA

$A_a$ = attitude toward asking the physician for a prescription for a specific drug product

$SN_j$ = subjective norm of the individual

$PBC$ = perceived behavioral control in a given situation.

$BI$ = behavioral intention of the target behavior

$B$ = target behavior exhibited

Figure 4: Final Research Model to be Tested
The study model presented in Figure 4 illustrates the framework for the three study models tested in Chapter 4, research question 4. Each of the three study models tested in Chapter 4 contains the same constructs, but each will be adjusted as the behavior of interest changes. For each of the three models, the three attitudes constructs will remain the same. The subjective norms and perceived behavioral control constructs, however, will change between the second and third models. These constructs change to reflect the changes in the behavior of interest between the second and third models.

For the first two models, the behavior of interest is obtaining a prostate exam. The five independent variables (three attitudes, subjective norms, and perceived behavioral control) and the actual behavior will remain the same. The only difference between the first two models is in the level of behavioral intent. The behavioral intent of obtaining a prostate exam essentially remains the same between the models, except that the level of effort by the patient changes. In the first model, the behavioral intent question
asked the consumer about obtaining a prostate exam at their next scheduled doctor’s appointment. The behavioral intent question used in the second model asked the consumer about making a special appointment to obtain a prostate exam. Thus, the level of behavioral intent in the second model requires more effort by the consumer. These measures will demonstrate whether changing the level of effort required in the behavioral intent actually affects the total variance explained by the model.

The third model will contain a different behavior of interest. The behavior of interest in this model is whether the consumer actually had a prescription for the product advertised filled. The three attitude constructs remain the same as before. The items measuring subjective norms, perceived behavioral control, and behavioral intent will remain essentially the same. In these items only the wording will be changed to reflect the new behavior of interest.

Two different behaviors were included in the study for an important reason. The product specific ad may have worked in convincing the patient to go to the physician and
ask for the advertised product. However, a prostate exam may have showed the patient did not need treatment. In this case the ad worked, but the patient did not receive a prescription for the advertised product. The measurement of whether the patient received a prostate exam or not would partially correct this problem if differences between the groups were observed regarding this “intermediate behavior”.

The three model variations also allowed the investigation of Ajzen’s Theory of Planned Behavior from different perspectives. This multi-faceted approach can provide insight about the conditions under which Ajzen’s model is most useful.
CHAPTER III

METHODOLOGY

The methodology used in this study was divided into six broad categories: 1) sampling procedure, 2) data collection, 3) definition and measurement of variables, 4) research questions and hypotheses, 5) sources of error and bias, and 6) data analysis.

SAMPLING PROCEDURE

Target Population

The target population for this study was all men over age 55 in the U.S. The accessible population was male consumers between the ages of 60-75 in the database of AmericaList Inc., a mailing list company. All male consumers who were between the ages of 60-75 and Ohio residents within the database of AmericaList were eligible for inclusion in the study. The sample was limited to Ohio
residents due to financial constraints of the researcher, and the opportunity for increasing response rate, since the participants were informed the study was being conducted by The Ohio State University College of Pharmacy. The database of consumers used by AmericaList is updated every 90 days.

**Sample Size Calculation**

The size of the sample was calculated, using the method described by Pathak, Meinkhold, and Fisher (1980), from the equation:

\[ n = (Z_{\alpha} \cdot \sigma/e)^2 \]

where

- \( n \) = sample size
- \( Z_{\alpha} \) = standard normal distribution
- \( \sigma \) = population standard deviation
- \( e \) = acceptable level of error

The standard deviations of these measures in the population are not known. The estimated population standard deviations were determined using the range of the response choices divided by six (Pathak, Meinkhold, and Fisher 1980). Each of the components in the survey instrument used in the study were measured on a seven-point Likert-type scale. Therefore, the value of "\( \sigma \)" in the equation is equal to 1.

The desired alpha level for this study was chosen to be 0.05 and the level of error of ± 0.20 was considered to be
acceptable. Using the sample size equation above, the appropriate sample size was calculated to be:

\[ n = (1.96 \times 1/0.20)^2 = 96 \text{ per cell} \]

Since there are two treatment cells and one control group cell, the calculated sample size for the study is 288. Assuming a response rate of 25%-30% based on the response rates of the pilot test, 1093 men between the ages of 60 and 75 were sampled.

**Sample Selection**

A probability sampling technique was used in selecting individuals for inclusion in the sample. This technique helped to reduce selection bias and allowed the researcher to accurately measure sample error in the study.

The probability sampling technique utilized for this study was simple random sampling. This sampling technique was chosen because the computer system at AmericaList can be programmed to generate a simple random sample of 1093 from the male Ohio residents between the ages of 60 and 75.

There are some possible sources of sampling error beyond the control of the researcher. These may include the inaccuracies in information contained in the database of
AmericaList. This may include errors in the data entry of the consumers' age, address, and phone number.

**Human Subjects**

The study involved human subjects to the extent that the subject agreed to and completed the mailed questionnaire. Subjects were assured that all responses remained completely confidential. The information collected through the use of a mailed questionnaire was used for research purposes only. Respondents also received a second questionnaire regarding actual behaviors five months after the advertisements had been mailed. These responses also remained completely confidential with patients being identified only by the code number assigned to their questionnaire responses. The study was submitted to and approved by the Human Subjects Review Committee of The Ohio State University.
DATA COLLECTION

Experimental Design

The study design consisted of two treatment cells and one control group cell. Each respondent selected for inclusion was randomly assigned to one of the three cells. Each of the two treatment cells was exposed to a different form of advertisement. Only one product specific advertisement, and one disease specific institutional advertisement with multiple exposures was used in the study. This method was chosen because of the research objective of overall advertising effectiveness and not the determination of which advertisements may be more effective than others. Figure 5 illustrates the study design that was used.
\[ R_1 \ X_1 \ X_1 \ X_1 \ O_1 \]
\[ R_2 \ X_2 \ X_2 \ X_2 \ O_2 \]
\[ R_3 \ \ \ \ \ \ O_3 \]

where:

\( X_1 \) - a product specific advertisement for Hytrin\textsuperscript{R}

\( X_2 \) - a disease specific institutional advertisement that illustrates the health benefits of having a prostate exam

\( O_1-O_3 \) - observation points

\( R_1-R_3 \) - random assignment of study participants

**Figure 5: Post Test Only with Control Group Design**

These specific treatments were chosen because of their previous extensive use by the pharmaceutical industry.

Direct mail was chosen as the preferred media in exposing the respondents to the promotional material. Direct mail is commonly used when a firm has a mailing list containing the names of individuals with some common characteristic (Guiltnan, 1991). Direct mail was an economical way of reaching a specific audience with complex messages when the target audience is identifiable and accessible. Direct mail promotions allowed the consumer as
much time as needed to read and process the information in the promotional material. Other factors, such as time and cost considerations, also were factored into the decision by the researcher to use direct mail for this particular study design.

The typical finding in attitude repetition research is an inverted U-shaped relationship between attitudes and repetition (Berger and Mitchell, 1989). With reasonably complex ads—ones that require a large amount of processing by the consumer—attitude strength increases initially, but "wear out" occurs with further repetition (Cacioppo and Petty, 1979). The most common explanation for this relationship is that consumers require a number of repetitions to fully comprehend and process the message of reasonably complex advertisements. Previous research has shown that subjects generate positive thoughts about the message over low to moderate levels of exposure frequency. This results in more favorable attitudes (Berger and Mitchell, 1989). However, at some point, individuals tend to become inattentive to the message, eventually leading to the formation a negative reaction towards the advertisement, causing a decrease in the favorable attitude towards the product.

Berger and Mitchell (1989) found that consumer attitudes towards a product became significantly more
accessible, easier for the consumer to recall, and consumers' exhibited a significantly higher degree of confidence after as few as three exposures to an advertisement. Their results also showed that attitude-behavior correlations increased significantly between one and three exposures to an advertisement, but exhibited no gain between three and four exposures. Based on past research, this study used three exposures for each of the treatment groups. Each exposure was sent one week apart for a total of three weeks. This spacing in time between interventions was chosen primarily due to study length considerations.

Subjects assigned to the first treatment group received advertisements for Hytrin®. The same advertisement was used for all three exposures. Due to the pre-clearance necessary for DTCA and the nature of the study (field setting), an advertisement that had already been approved by the FDA was used. The researcher had no control over the information included in the advertisement, but chose which advertisement was used in the study and to whom it was sent. The decision on the advertisement to be used was a joint decision between the researcher and the dissertation committee. The advertisement provided in Appendix A was the unanimous choice of the researcher and dissertation committee.
Subjects assigned to the second treatment group received a disease specific institutional advertisement regarding BPH. The same advertisement was used for all three exposures. A disease specific institutional advertisement contains no product specific information. These advertisements contain only information about the disease state and statements regarding the availability of treatment alternatives without mentioning any product names. These types of advertisements are often used as patient education tools.

A disease specific institutional advertisement was included because health care professionals feel this form of DTCA is most beneficial to the patient (Scheman, 1993). This type of non-specific advertisement increases patient awareness of a current disease state and encourages them to seek treatment to improve their health. This type of advertisement also is most often used by a manufacturer that is a market leader in a particular drug category or for a product with no existing competition. Hytrin® is the preferred pharmacological treatment alternative for BPH (Banna and Rushdi, 1993). Since Abbott Laboratories has never used a disease specific institutional advertisement for BPH, the researcher designed an advertisement based on patient education materials provided to the researcher by Abbott Laboratories and the design of other disease specific
institutional advertisements for BPH. A copy of the disease specific institutional advertisement is provided in Appendix B.

Subjects assigned to the third group comprised the control group. This group did not receive either the product specific advertisement for Hytrin R nor the disease specific institutional advertisement regarding BPH from the researcher. The control group did, however, receive the same research survey instrument as the two treatment groups.

Type of Instrument

There were two questionnaires used for data collection. The first was a self-administered, mailed questionnaire. The questionnaire measured attitude towards DTCA, attitude towards Hytrin R, attitude towards asking the physician for a prescription for a specific product, importance of significant others in health decisions, perceived behavioral control over health behaviors, and the behavioral intent of the patient to ask the physician for a prostate exam and/or a prescription for Hytrin R. The quantity of information needed, financial constraints, time constraints, and wide geographic distribution of the respondents eliminated the possible use of telephone or personal interviews as alternatives for data collection.
A panel of experts was used to assess the face and content validity of the instrument to minimize non-random error. The panel of experts included members of the dissertation committee. These members represent a diverse group with expertise in each of the following areas; instrument design, consumer behavior, DTCA, and attitude assessment and measurement. The panel of experts were asked to comment on design, format, wording, length, and items used to measure the constructs. These individuals also assisted the researcher in the evaluation of individual items in the questionnaire.

After the panel of experts provided their comments on the instrument, a field test was conducted to further assess the content and face validity. Graduate students and other faculty in the Division of Pharmacy Practice and Administration at The Ohio State University College of Pharmacy were used for the field test. Ten individuals were selected and utilized at this step. The individuals selected by the researcher were asked to comment on the instrument as a whole assessing the design, readability, and process of completing the instrument. These individuals were not asked to complete the questionnaire. The instrument was revised based on comments from the panel of experts and the results of the field test.
Finally, a pilot test was conducted using a subsample of the target population. One hundred individuals were included in the pretest. Fifty were sent a copy of the advertisement for Hytrin® along with the questionnaire and fifty were sent just the questionnaire. Sample size, as well as instrument revisions, were adjusted based on the results of the pilot test. The following revisions were made based on the results of the pilot test.

Our response rate for the pilot test was low, only 15% usable responses. The researcher believed this low response rate was due to several reasons. Originally, some of the questions in the study contained direct references to the product Hytrin®. Based on comments on the returned questionnaires, many participants in the pilot test did not respond because they thought the entire questionnaire was about Hytrin®. Therefore, if they were not familiar with the product, they didn’t feel they could respond to the questionnaire accurately. For example, the wording on the questions measuring the construct asking the physician for a prescription for a specific drug was changed. The questions originally asked the respondent about asking for a prescription for Hytrin®. The wording was changed to asking the physician for a prescription for a specific product.

Also, section two dealt entirely with attitudes toward the product Hytrin®. Many of the respondents in the pilot
answered section one, but stopped responding to the questions in section two and beyond. Based on this information a “qualifier” question was included before the attitude toward Hytrin® questions were asked. The qualifier asked the respondent if they had ever heard of the drug Hytrin® used to treat BPH. If the answer was no, they were instructed to skip to section 3. If the answer was yes, they were instructed to finish the rest of section 2.

Finally, in section six (risk information retention questions), a “Don’t Know” response was included in addition to the true or false responses. On the pilot test, many respondents left this section blank or wrote in “don’t know” because they did not know the answer. These changes along with a strong cover letter on colored Ohio State University stationary were believed to be help increase the response rate.

Item Sequence and Physical Characteristics

The questionnaire consisted of six sections in an attempt to measure and provide explanation for each part of the model tested. Each section used a seven-point Likert-type scale for all responses.

The ordering of the sections of the questionnaire was designed based on the progression and direction of the study.
model and the order used in previous studies using similar instruments (Morris et al. 1986a and 1986b). The ordering of these sections was refined based on results and recommendations of the panel of experts, the field test, and the pilot test. A copy of the questionnaire is included in Appendix C.

The order of the sections included in the questionnaire were as follows:

1) attitude toward advertising prescription drugs directly to the consumer in magazines, newspapers, direct mail, and television and attitude toward asking your doctor for a prescription for a specific product,

2) attitude toward the product Hytrin®

3) importance of significant others in health decisions (subjective norms),

4) perceived control over health behaviors,

5) behavioral intent in obtaining a prostate exam and asking for a prescription for Hytrin® if the prostate was enlarged and treatment was needed,

6) additional comments,

7) a true-false knowledge test of risk information retention, and

8) demographics.
The final form of the questionnaire was reproduced in booklet form, back-to-back on 8 1/2" X 11 white paper.

**Questionnaire Administration**

Questionnaire packets were mailed to all of the individuals who were randomly selected for inclusion in the study. Each questionnaire was coded (numbered) to facilitate the matching of responses with the second questionnaire of actual health behaviors. The researcher assured that all responses would remain confidential. Included in each packet was a cover letter explaining the importance of the study, a copy of the questionnaire, an incentive (a certified Ohio State Buckeye sportsfan certificate), and a return postage-paid envelope. The cover letter asked the respondents to complete and return the survey within two weeks and contained an assurance of confidentiality. Two weeks after the first mailing of the questionnaire, a second questionnaire with a different cover letter was sent to those who had not yet responded. The cover letters used in the study are provided in Appendix D.
Health Behavior Data Collection

The final part of the study was the collection of data to determine which individuals actually received a prescription for Hytrin\textsuperscript{R} or saw a physician for a prostate examination. As a control measure, the utilization of other products for BPH, such as Proscar\textsuperscript{R} and Cardura\textsuperscript{R}, also was determined. This was important due to possible physician preference for a different treatment alternative. This demonstrated that the individual was motivated by the advertisement to see their physician about a possible prostate problem indicating the possible effectiveness of the advertisement.

This information was collected via a second short questionnaire sent only to respondents of the first questionnaire. It was collected five months after the last advertisement was mailed. The respondents were asked a variety of health related questions so that the information needed for the study was blinded. For example, the respondents were asked if they had had their blood pressure checked by their physician, cholesterol measured by their physician, and/or had been given a prostate exam by their physician within the last five months. Each respondent was also asked if he had had a new prescription filled for Hytrin\textsuperscript{R}, Proscar\textsuperscript{R}, Cardura\textsuperscript{R}, Zantac\textsuperscript{R}, Vasotec\textsuperscript{R}, and/or amoxicillin within the last five months. Two weeks after
the questionnaire was mailed, a different cover letter and second questionnaire was mailed to the non-respondents.

DEFINITION AND MEASUREMENT OF VARIABLES

The purpose of this study was to determine the effectiveness of DTCA. Effectiveness can be measured in several ways. This may include, but is not limited to, measuring patient attitudes, subjective norms, perceived behavioral control, behavioral intent, and/or observing actual behaviors. Through a combination of two mailed questionnaires, this study gained insight into the effectiveness of product-specific and disease-specific institutional advertisements.

The independent variables for the study were attitude toward DTCA, attitude toward the product Hytrin®, attitude toward asking the physician for a prescription for a specific product, subjective norms, and perceived behavioral control. In the analysis of responses given on the first questionnaire, behavioral intent was the dependent variable. In the analysis using the data collected from the second questionnaire, behavioral intent was the independent variable and the two actual behaviors, obtaining a filled prescription for Hytrin® and having a prostate exam, were the dependent variables.
The study model indicated that a patient's attitude toward a prescription drug product that has been advertised to consumers is multi-dimensional. Past research (Brinberg and Morris, 1987; Morris, 1984; Morris, Brinberg, Klimberg, et al, 1986a and 1986b; Perri and Dickson, 1988; Perri and Dickson, 1987; Perri and Nelson, 1987) suggest that a patient's attitude is single dimensional comprised of several constructs. In the studies conducted by Morris, (1984) and Morris, Brinberg, Klimberg, et al, (1986a and 1986b), several different constructs have been shown to be distinct through factor analysis. A complete discussion of the segmentation of the attitude construct into three separate constructs is given in the section entitled, “The Study Model” in Chapter 2. The three separate attitude constructs were: 1) attitude toward DTCA, 2) attitude toward asking the physician for a prescription for a specific product, and 3) attitude toward the product HytrinR.

**Attitude Toward Direct-to-Consumer Advertising**

Attitude toward DTCA is defined as the degree to which the consumer has a favorable or unfavorable evaluation or appraisal of any prescription drug through consumer directed media (Ajzen, 1991). This includes radio, magazines, newspapers, television, and direct mail. This construct has
been measured reliably in past studies by Morris et al, (1986a and 1986b) and Perri and Nelson (1987). These studies used a series of items that were summated to give an overall attitude toward DTCA score. In these studies, the researchers felt that a multiple item measure may provide a more accurate description of the consumer’s overall attitude toward DTCA. This construct was measured in section one of the research instrument.

The first part of section one measured attitude toward DTCA using 14 different items (items a-n). These items were measured using a seven-point Likert type scale (1 = strongly disagree to 7 = strongly agree). Eleven items were used from the Morris et al study, (1986a) and three items were used from the Perri and Nelson study, (1987). These items were the only ones distinctly different from those used in the Morris et al study, (1986a).

The coefficient alpha for the Perri and Nelson (1987) instrument was calculated to be 0.87 and therefore is assumed to be reliable. The instrument used by Morris et al. (1986a and 1986b) did not report a coefficient alpha for their measure. The researcher contacted Dr. Morris at the FDA Division of Drug Marketing, Advertising, and Communication². Dr. Morris informed the researcher that

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² Based on a conversation with Dr. Morris June 8, 1994
reliability was not calculated for the instrument. Dr. Morris felt from the results and the factor analysis that the instrument was adequately reliable. Therefore it was decided that Dr. Morris' instrument would be appropriate to use in this study.

These 14 items were summated and used as the respondents' overall score for attitude toward DTCA. The potential range of the summated scores was from 14 to 98. The higher the score the more positive the respondents' attitude toward DTCA. An example of one item from section one part one of the research instrument provided in Appendix C is “I would like to see more advertisements for prescription drugs.”

Attitude Toward Asking Your Physician for a Prescription for a Specific Product

The second part of section one measured the attitude toward asking your physician for a prescription for a specific product. This construct is defined as the degree to which a consumer has a favorable or unfavorable evaluation or appraisal of this behavior (Ajzen, 1991). This was a very important part of the study. The consumer may have a positive attitude toward the product Hytrin and a positive attitude toward DTCA, but would never confront
the physician by recommending the use of a particular therapy. If this is the case, the model breaks down and the DTCA is ineffective based on this one construct. Therefore, it was decided to include a separate measure for this attitude construct based on research by Morris et al. (1986). This may be especially true in the study population, males aged 60-75. Older individuals may be less likely to question their physician or make therapy recommendations.

Four items were used to measure the respondent's attitude (items o-r). These items were measured using the same seven-point Likert type scale previously discussed. These items were the same ones used by Morris et al., (1986a and 1986b). Only the name of the product was changed. As in the previous sections, a coefficient alpha was not calculated, but Dr. Morris felt that the study results and the factor analysis provided adequate rational that the instrument was reliable.

These items assessed respondent agreement or disagreement with statements such as comfort level in asking his doctor for a prescription for a specific product and of the refusal of his request of the doctor to prescribe a specific product would; 1) make the respondent upset with the doctor, 2) make the respondent upset with himself for asking, 3) cause the respondent to switch doctors, or
4) reinforce the respondent to follow the doctor’s advice.

These four items were summated and used as the respondent’s overall score for attitude toward asking the physician for a prescription for a specific product. The potential range of the summated scores was from 4 to 28. The higher the score the more positive a respondent’s attitude. An example of one item from section one of the research instrument provided in Appendix C is “If I asked my doctor to prescribe Hytrin™ and he/she refused, I would be upset with my doctor for refusing my request.”

**Attitude Toward the Drug Product Hytrin™**

Attitude toward the drug product, Hytrin™, is defined as the degree to which a consumer has a favorable or unfavorable evaluation or appraisal of the product (Ajzen, 1991). Section two measured the respondent’s attitude toward the product Hytrin™ using 13 items (items a-m). These items were measured using the same seven-point Likert type scale previously discussed. These items are the same items used in the Morris et al. study, (1986a and 1986b). Only the name of the product was changed. Again, a coefficient alpha was not calculated, but Dr. Morris felt that the study results and the factor analysis provided adequate rational that the instrument was reliable.
Section two asked the respondent’s agreement or disagreement with statements regarding Hytrin’s® safety, effectiveness, willing to use Hytrin® for BPH, comfort in asking the physician for more information or his opinion of the drug, use of the product if prescribed, willingness to follow the doctor’s advice, preference of other drugs for BPH, risk versus benefit of using Hytrin®, and perceived seriousness of BPH.

These 13 items were summated and used as the respondents’ overall score for attitude toward the drug product, Hytrin®. The potential range of the summated scores was from 13 to 91. The higher the score the more positive a respondent’s attitude toward the drug product Hytrin®. An example of one item from section two of the research instrument provided in Appendix C is “Overall, the benefits of using Hytrin® outweigh the risks.”

Subjective Norms

Subjective norms of consumers are defined as the perceived social pressure to perform or not to perform a given behavior (Ajzen, 1991). The subjective norm of the consumer is composed of two variables, the normative belief of some referent group or individual and the motivation to comply with that referent group(s) or individual(s).
Normative beliefs are defined as the likelihood that an important referent group(s) or individual(s) approve or disapprove of performing a given behavior (Ajzen, 1991). The motivation to comply component measures the consumer’s desire to exhibit or not exhibit the behavior regarded as appropriate by the referent group(s) or individual(s). The normative belief is multiplied by the consumer’s motivation to comply with that referent group(s) or individual(s).

Ried and Christensen, (1988) identified three referent groups (individuals) that affect a consumer’s health related behavior. These groups (individuals) were family, friends, and the patient’s physician. These three referent groups (individuals) will be included in this study. The pharmacist may be another potential referent individual that may have an impact on health related behaviors. Therefore this study measured the motivation to comply with four referent groups (individuals). These were family, good friends, the patient’s physician, and the patient’s pharmacist.

Ried and Christensen’s items used to measure motivation to comply with the referent group(s) or individual(s) were found to be reliable with a coefficient alpha of 0.75. Therefore, these items were used in this study. An example of an item to be used to measure motivation to comply from
section 3 of the questionnaire in Appendix C is “Generally speaking, I want to do what my family thinks I should do.”

Two normative beliefs based on two separate behaviors were included in the study. The two behaviors of interest were whether the consumer should have a prostate exam and whether the consumer should ask the physician for a prescription for Hytrin® if the patient develops an enlarged prostate. These normative beliefs were measured for each referent group (individual).

These items were adapted for this study based on the instrument used by Ried and Christensen, (1988). Their instrument assessed the normative beliefs of a patient's drug-taking behavior. The measurement of the normative beliefs in the instrument was found to be reliable with a coefficient alpha of 0.74. Examples of items measuring each of normative beliefs are: 1) generally speaking, my family thinks I should have a prostate exam and 2) generally speaking, my family thinks I should ask my doctor for a prescription for Hytrin® if I develop an enlarged prostate.

The subjective norms of the respondents were measured in section three. This section contained 12 items (items a-l) using the same seven point Likert type scale. Four questions consisted of the motivation to comply with the four reference groups (individuals). Eight items assessed 1) the normative belief to see a doctor about prostate problems
and 2) the normative belief to ask the physician for a prescription Hytrin® for each of the four referent groups (individuals).

The subjective norm score was the summated product of the motivation to comply score and the normative belief score (Ried and Christensen, 1988). The potential range of the summated scores was from 2 to 98 for each referent group (individual) and a range 4 to 392 for all referent groups (individuals) summed together. The higher the score the more influence individual(s) or group(s) had on the consumer’s health related behaviors. Refer to Appendix C, section three, for the complete instrument used to measure subjective norms.

Perceived Behavioral Control

Perceived behavioral control is defined as the perceived ease or difficulty of performing a given behavior (Ajzen, 1991). Ajzen and Madden (1986) identified five components that comprise an individual's perceived behavioral control in an specific situation. These are obligation, motivation, ability, time, and need of assistance. An item to measure a patient’s obligation was excluded from the questionnaire since this component does not apply to asking a physician for a prescription. There
was one item each to measure motivation, ability, time and need of assistance for each of the two behaviors. The perceived behavioral control items used the same two behaviors as the subjective norms measures, obtaining a prostate exam and obtaining a prescription for Hytrin®. An example of two items used are 1) “I have the ability to convince my doctor to write me a prescription for Hytrin® if I wanted to” and 2) “I have the ability to convince my doctor to give me a prostate exam.”

Ajzen also suggests that items using direct measures of perceived behavior control should be used. Ajzen and Madden (1986) used three such items. Therefore, this study used three items, adapted from theirs, to directly assess control. The first item directly asked the respondent how much control they have in obtaining a prostate exam. The next two directly asked the respondent how much control they have in obtaining a prescription for Hytrin® from their physician.

The items used in this study were adapted from the instrument developed and used by Ajzen and Madden (1986). The instrument was modified slightly for this study population. Ajzen and Madden (1986) originally used their perceived behavioral control instrument to measure control of students to attend class and control of students to get an A in a course. To date, well controlled studies with
reliable instruments that measure perceived behavioral control in a health behavior setting have not been conducted. This may be because the Theory of Planned Behavior is less than ten years old. An adapted version of the instrument by Ajzen and Madden (1986) was chosen because the coefficient alpha for the instrument was 0.74 and deemed acceptable for this study.

The 11 items (items a-k) in this section used the same seven-point Likert type scale. The perceived behavioral control score was the summated score of all 11 items. Comparison and analysis was made between the eight items measuring the four factors of perceived behavioral control and the three items directly measuring perceived behavioral control. The potential range of the summated scores was from 11 to 77. The higher the score the more perceived control the respondent has regarding these specific health related behaviors. Refer to Appendix C, section four, for the complete instrument used to measure perceived behavioral control.

Behavioral Intent

Behavioral intention is defined as the consumer’s predisposition or probability of reacting a certain way when presented with an opportunity to perform a specific behavior
(Ajzen, 1991). The measurement of behavioral intent is dependent on the behavioral situation being researched. Therefore it is difficult to use instruments used by other researchers who studied different behavioral situations. Behavioral intention is used as a surrogate endpoint when the researcher is unable to observe the consumer's actual behavior.

Section five measured the behavioral intent or "probability" of 1) the behavioral intent of asking the physician for a prostate exam and 2) the behavioral intent of asking the doctor for a prescription for Hytrin® if the consumer's prostate was enlarged and needed treatment. The behavioral intent of obtaining a prostate exam was measured using two items (items b-c) with different levels of effort and involvement required by the patient. The two levels of involvement were: 1) getting a prostate exam at my next scheduled appointment, and 2) making a special appointment with my doctor to have a prostate exam. Responses gave insight into the amount of effort a consumer may be willing to expend to obtain a prostate exam. An example of an item is "I intend on asking my doctor to give me a prostate exam at my next scheduled appointment." A fourth item (item d) was also included to determine if the pharmacist had any effect in the behavior intent of the patient to receive a prostate exam for purely exploratory purposes.
Section five concluded with one item (item e) regarding the patient’s choice of a product if a prostate exam demonstrates a need for treatment. This item was “If a prostate exam showed my prostate was enlarged and I needed treatment, I would ask my doctor for a prescription for Hytrin®.”

Each behavioral intent question was measured using the same seven-point Likert type scale. The range of scores for each item 1 to 7. The higher the score the higher the probability of the patient obtaining a prostate exam or asking for the product Hytrin®. Refer to Appendix C, section five, for the complete instrument used to measure behavioral intent.

**Retention of Risk Information**

Section 6 measured retention of risk information using true-false knowledge test of 10 items. Risk information is defined as information regarding side effects, adverse effects, or other precautions in using the drug (Morris et al. 1986b). This is the same test of recall used by Morris et al. (1986b). This section was included at the request of Dr. Nancy Ostrove, Head of Direct-to-Consumer Advertising at the FDA. Dr. Ostrove was interested in the amount of risk information consumers retain from DTCA. Risk retention
information also was used as an intermediate measure of effectiveness from a public policy perspective in the study. This section was modeled after the instrument used by Morris et al, (1986b). The respondent answered true, false, or don’t know for each item. Items included five factual pieces of risk information, and five non-factual pieces of risk information based on the advertisement presented in Appendix A. Two factual and two non-factual pieces of risk information were included based on information contained within the advertisement. Three factual and three non-factual pieces of risk information were included based on information presented in the brief summary. There was no cross-over of risk information included between the advertisement and the brief summary. Comparisons were made between the treatment group receiving the product specific advertisement and the group receiving the disease specific institutional advertisement and control group.

Demographics and Background Information

Demographic information was obtained to ascertain information about each respondent. Marital status, education level, size of their of residence area, and income level information were collected. Gender was excluded because our population was males. Age was measured to ensure that the
respondents were within the sampling frame ages of 60 to 75. Also, basic recall information was collected. Four drugs, Hytrin®, Proscar®, Glucotrol®, and Lasix®, along with a choice of not having seen any advertisements for prescription drugs, were presented. The respondent was asked to circle the drugs he had seen advertised in the past. Hytrin® and Proscar® have been advertised in the past and Glucotrol® and Lasix® have not. This assessed if the consumer recalled seeing the advertisement sent through the mail for Hytrin®. Demographics were also used to assess the equivalency of the three randomized groups.

RESEARCH QUESTIONS AND HYPOTHESES

Research Question 1

What is the effect of a product specific advertisement or a disease specific institutional advertisement on a consumer’s attitude toward DTCA, attitude toward the product, and attitude toward asking the physician for a prescription for a specific drug product?

Perri and Nelson (1987) measured overall attitude toward DTCA, as part of a larger study. They did not measure
the ability of DTCA to affect attitude toward the product. They found that patient attitudes towards DTCA were favorable. Brinberg and Morris (1987) and Morris, Brinberg, Klimberg, et al. (1986a and 1986b) also conducted studies measuring patient attitudes toward DTCA. These studies found that patients were generally favorable toward DTCA.

This study will further validate the initial work of Morris et al. (1986a and 1986b) to assess whether the patient’s attitude was multi-dimensional and was comprised of three different attitudes, each of which may be affected differently and independently by DTCA. Previous studies also failed to provide a comparison group (control group) to demonstrate the amount or level of change DTCA has on each of the three patient attitudes in this study. The specific hypotheses tested under Research Question 1 include:

H 1.1: There is a difference in the consumer’s attitude toward DTCA among the three treatment groups (product specific advertisement group, disease specific institutional advertisement, and the control group).
H 1.2: There is a difference in the consumer's attitude toward the product, Hytrin, among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).

H 1.3: There is a difference in the consumer's attitude toward asking the physician for a prescription for a specific product among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).

Research Question 2

What is the effect of a product specific advertisement or a disease specific institutional advertisement on a consumer's subjective norms, perceived behavioral control, behavioral intent, and actual behavior?

Past research demonstrates that a person's subjective norms provide a significant contribution to the variance explained in a specific behavior (Ajzen and Fishbein, 1980). Therefore, the subjective norms of the consumer's may help
to explain the variance in exhibition of health-related behaviors (Ried and Christensen, 1988).

Perceived behavioral control is an important construct that adds to the explanatory power of the Theory of Reasoned Action (Ajzen, 1991). This is especially true when the given behavior of interest in not under the complete volitional control of the consumer (Ajzen, 1991).

The measurement of behavioral intent is a surrogate endpoint when the researcher cannot be present when the actual behavior is exhibited. However in this study, data was obtained regarding actual behaviors. Therefore, responses of behavioral intention were analyzed and correlated with whether the actual behavior was exhibited or not. This will contribute to the literature regarding the usefulness of behavioral intent as a surrogate endpoint in explaining and predicting health related behaviors. The specific hypotheses tested under Research Question 2 include:

H 2.1: There is a difference in the consumer’s subjective norms among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).
H 2.2: There is a difference in the consumer's perceived behavioral control among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).

H 2.3: There is a difference in the consumer's behavioral intent to ask the physician for a prostate exam among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).

H 2.4: There is a difference in the consumer's actual behavior of obtaining a prostate exam among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).

H 2.5: There is a difference in the consumer's behavioral intent in asking for a prescription for Hytrin® if a prostate exam shows the patient's prostate was enlarged among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).
There is a difference in the consumer’s actual behavior in obtaining a prescription for Hytrin® among the three treatment groups (product specific advertisement group, disease specific advertisement group, and the control group).

Research Question 3

Are there relationships or inter-relationships between attitude towards DTCA, attitude toward the product, attitude toward asking the physician for a prescription for a specific drug product, a consumer's subjective norms, and perceived behavioral control?

Past research has suggested that there may be relationships or inter-relationships between variables in the Theory of Planned Behavior depending on its application (Ajzen, 1991). The extent of these relationships varied from situation to situation depending on the behavior in question. Therefore, for DTCA the potential relationships between the independent variables were investigated.

The are relationships between the independent variables in the study model.
Research Question 4

Does the data set fit the proposed study model using multiple regression testing and correlational analysis?

Multiple regression analysis was used to determine if the data set fits the proposed study model. The amount of variance explained was used to determine the explanatory power of the model hypothesized. In addition, correlational analysis was used to test the fit between behavioral intention and the reported behavior.

H 4.1: The amount of variance explained by the study models is statistically significant.

Research Question 5

Do consumers retain risk information from advertisements for prescription drug products?

Morris et al. (1986b) found that type of media, phrasing of risk information, and the format of the advertisements influence both recall and description of risk
information. However, the researchers do make the point that the artificial nature of the testing circumstances do limit the conclusions of the study. The study specifically found that television advertisements were more effective at conveying risk information than magazine advertisements and of specific risk information led to a greater recall than general risk information. General risk information in the advertisements were found to be no more informational than the control group. Finally, the separation of risk information from the advertisement resulted in lower recall scores than advertisements in which the risk information was integrated within the advertisement. Overall, specific risk information is more informative than general risk information (Brinberg and Morris, 1987).

Another study by Tucker and Smith, (1987) suggested that the advertisement which contained the brief summary information with headings was judged to have higher information value by the respondents which was the only advertisement significantly different in informational value from the advertisement with no risk information. The results further suggest that advertisements with general risk information and no risk information and advertisements with brief summary headings and a narrative brief summary formed homogenous subsets regarding sense of security presented by the advertisement. These two subsets were
significantly different regarding sense of security presented by the advertisement. Also, those advertisements with no risk information or general risk information were judged as providing more security to the consumer than those which contained detailed risk information (Tucker and Smith, 1987).

The study also found that those advertisements that contained any amount of risk information were found to be more appealing by consumers than advertisements which did not contain any risk information. Finally, the study did not find any significant differences between the advertisements regarding the clarity of the information presented (Tucker and Smith, 1987).

These studies provide valuable insight into the perception of risk information, but recall of risk information was not clearly demonstrated. Also, these studies did not ascertain where the consumer obtained this recalled risk information. Determinations need to be made as to the consumer’s recall risk information. Therefore, the research hypothesis related to Research Question 5 was:
H 5.1 There is a difference in the retention of risk information among the three treatment groups (product specific advertisement group, disease specific institutional advertisement, and the control group).

**SOURCES OF ERROR AND BIAS**

There were several sources of error in the study that had to be considered. These types of error involved the researcher, the respondents, and/or the instrument. The most common sources included: 1) sampling frame error, 2) data processing errors, 3) instrument design errors, 4) subject consistency, 5) social desirability, and 6) nonresponse errors.

**Sampling Frame Error**

The sampling frame used in the study included all male Ohioans between the ages of 60 and 75 that were contained in the database of AmericaList. It was expected that some errors existed within this database. Age was measured in the demographics section to assess if each respondent was between the ages of 60 and 75.
Data Processing Errors

Data processing errors were defined as those errors associated with coding and transcribing responses from the study instrument. To minimize the effects of these errors, all coding and transcribing of the data was completed by the researcher and doubled-checked.

Instrument Design Errors

Misleading or ambiguous questions and/or unclear instructions may affect the responses given by the study participants. The questionnaire was reviewed by a panel of experts, pilot tested, and field tested to identify potential problems with questions used in the study instrument. Also, there may be measurement error or construct error with the study since items were borrowed from very similar, but still somewhat different, studies.

Subject Consistency

The mood, attitude, and motivation of the respondent may change during the course of completing the research instrument. Also, situation factors, such as interruptions and changes in the environment, may have affected the
responses of the study participants. These errors were difficult to measure, but could be done through a test-retest method.

Social Desirability

This source of bias occurs when the respondent gives the most socially desirable or politically correct response which, in turn, may not represent the respondent’s true response. This was minimized by ensuring the respondents that their responses were confidential and anonymous to everyone except the researcher.

Nonresponse Errors

Low response rates may produce error into the results due to differences between nonrespondents and respondents. To minimize nonresponse, questionnaires were sent bulk mail, materials were personally signed by the researcher, and a second questionnaire was sent to nonrespondents, a cover letter stating the importance of the response on colored Ohio State University letterhead, an assurance of confidentiality was included with the questionnaire, and a small incentive (Professional Sportfan Certificate). Nonresponse error was assessed by comparing the first 10% of
the respondents with the last 10% of the respondents. This analysis produced no statistically significant differences between the two response groups.

DATA ANALYSIS

First, response rates were reported for each of the two questionnaire mailings. Then construct reliability and validity were assessed for each of the six constructs: attitude toward DTCA, attitude toward the product Hytrin®, attitude toward asking the physician for a prescription for a specific product, subjective norms, perceived behavioral control, and behavioral intent.

Descriptive statistical analysis was conducted for each individual item and summated scale. This provided means and standard deviations for all the variables. This also allowed an interpretation of the normality of the data to be made.

Demographic statistics were calculated for the data set in order to give the researcher actual demographic composition of the data set. Chi-square analysis was conducted to determine if there were demographic differences among the three study groups. Chi-square analysis also was conducted to determine if significant demographic
differences were observed for the five independent variables, three attitudes scores, subjective norms, perceived behavioral control, and the two dependent variables, {behavioral intent and actual behavior}.

After all the subsequent analyses had been performed, analysis of each research question and its hypothesis was conducted. Each hypothesis was stated in the alternative form, but the null form was statistically tested. Research questions 1 and 2 were analyzed using analysis of variance. This determined whether the significant differences among the treatment groups were observed on the three attitude scores, the subject norms, perceived behavioral control, behavioral intent, and actual behavior. Analysis of variance of recall of advertisements seen and between the subjective norm score calculated for each of the four referent groups was conducted to determine any differences.

A post hoc analysis using least significant difference (LSD) and Scheffe’s multiple comparison test was conducted to determine where the significant differences were. These are multiple comparison procedures used for testing test the null hypotheses that each possible pair of treatment means
are equal. These tests were chosen over Tukey's HSD Test because of its major limitation that all the samples must be the same size.

Research question 3 was analyzed using correlational analysis. This analysis determined the relationships or inter-relationships between the five independent variables in the study: attitude toward DTCA, attitude toward the product Hytrin®, attitude toward asking the physician for a prescription for a specific product, subjective norms, and perceived behavioral control.

Research question 4 was analyzed using multiple regression analysis. This determined the explanatory power of the model. Correlation analysis and logistic regression also were used to determine the relationship between behavioral intent and actual behavior. A path analysis approach was not used since the model contained a mix of continuous and discrete variables, namely behavioral intent and actual behavior.

Research question 5, the retention of risk information, was analyzed using Chi-square analysis to compare the number of correctly identified risk statements, the number of
incorrectly identified risk statements, and don’t know responses among the three groups for each question. Analysis of variance was used to determine the differences of the composite score, comprised of the number of correct answers for all ten questions, among the three groups. Chi-square analysis also was conducted using categorization of respondents by whether they had taken the product Hytrin\textsuperscript{R} in past and whether they had seen an ad for Hytrin\textsuperscript{R} in the past three months for each question. The four groups in this Chi-square analysis were: 1) had not taken Hytrin\textsuperscript{R} and had not seen an ad for Hytrin\textsuperscript{R}, 2) had not taken Hytrin\textsuperscript{R} and had seen an ad for Hytrin\textsuperscript{R}, 3) had taken Hytrin\textsuperscript{R} and had not seen an ad for Hytrin\textsuperscript{R}, and 4) had taken Hytrin\textsuperscript{R} and had seen an ad for Hytrin\textsuperscript{R}. Analysis of variance was also conducted for the composite score to determine the differences among the four groups.
CHAPTER IV

RESULTS

This chapter describes the results of the analyses and tests of the hypotheses for each of the five research questions. A short discussion of the results and hypothesis test for each question also is presented.

RESPONSE RATE

By September 1, 1995, a total of 303 questionnaires had been returned from the original sample of 1093 for the first questionnaire. Of the 1093 in the original sample, 13 were returned as undeliverable and 8 were deceased. This questionnaire measured attitudes, subjective norms, perceived behavioral control, behavioral intent, risk
information retention, and demographics. Of the 303 questionnaires that were returned, 296 were usable for all or part of the following analysis. This represents a response rate of 27.1%. A second questionnaire measuring actual behaviors was sent to the 296 respondents of the first questionnaire. The response rate for the second questionnaire was 260 or 87.8%.

RELIABILITY

Reliability is the extent to which measures are repeatable (Nunnally 1978). The reliability of measures used in the study could have been assessed using several different techniques. Nunnally (1978) and Nelson (1980) describe several methods which can be used. The techniques described are; alternative form method, split-halves, test-retest method, and internal consistency method. Due to potential of sensitizing the study participants along with other considerations, the internal consistency method was chosen over the other three.
The most commonly used measure of internal consistency is Cronbach’s Coefficient Alpha.

\[ \alpha = \frac{k}{k-1} \{1 - \sum_{i=1}^{k} \frac{\sigma_i^2}{\sigma_t^2}\} \]

where

\( k \) = number of related items

\( \sigma_i^2 \) = variance of item i among respondents

\( \sigma_t^2 \) = total variance of the scale among respondents

Cronbach’s Coefficient Alpha is based on the average variation among items and the total number of items. Nunnally (1978) suggests using Cronbach’s Coefficient Alpha for measuring internal consistency due to its conservative nature in estimating instrument reliability. This reliability estimate considers measurement error due to sampling content and situational factors accompanying the administration of items.

Cronbach’s Coefficient Alpha was calculated for each of the three attitude constructs, the two normative belief
scales (one for obtaining a prostate exam and one for obtaining a prescription for Hytrin®) and motivation to comply scale that comprise the subjective norm construct, and for the perceived behavioral control constructs (one for obtaining a prostate exam and one for obtaining a prescription for Hytrin®). The values for each of these variables are provided in Table 1.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient Alpha</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attitude toward DTCA (14)</td>
<td>0.78</td>
</tr>
<tr>
<td>Attitude toward Hytrin (13)</td>
<td>0.89</td>
</tr>
<tr>
<td>Attitude toward asking physician for a prescription for a specific product (3)</td>
<td>0.66</td>
</tr>
<tr>
<td>Normative belief of having a prostate exam (4)</td>
<td>0.83</td>
</tr>
<tr>
<td>Normative belief of having a asking the physician for a prescription for Hytrin (4)</td>
<td>0.88</td>
</tr>
<tr>
<td>Motivation to comply with the four referent groups (4)</td>
<td>0.71</td>
</tr>
<tr>
<td>Perceived behavioral control in convincing a physician to give a prostate exam (4)</td>
<td>0.72</td>
</tr>
<tr>
<td>Perceived behavioral control in convincing a physician to write a prescription for Hytrin (4)</td>
<td>0.32</td>
</tr>
</tbody>
</table>

{Number of items in each measure is provided in parentheses}

**Table 1: Coefficient Alpha Values - Final Measures**

The reliability estimates for most of the variables were acceptable. The high reliability estimates were most likely due to the fact that these measures had been used in a previous study by Morris et al. (1986a and 1986b) and found to be reliable based on factor analysis. (See Chapter
3 - Definition and Measurement of Variables). There were, however, two constructs that produced relatively low estimates of reliability.

Two of the three attitude constructs produced high estimates of reliability. One of the attitude constructs, however, was slightly problematic. The construct, attitude toward asking a physician for a prescription for a specific product, was problematic. The four items used to measure this construct were taken directly from a study conducted by Morris et al. (1986a and 1986b). The Cronbach Alpha for all four items was 0.56. The researcher felt that this was unacceptable and should be explained.

The first three items used to measure this construct specifically assessed the respondent’s feelings toward the physician if he/she refused a request for a specific prescription drug product. The fourth item, the problematic one, asked the respondent if he/she would be upset with themselves for making such as request. Further research into the study by Morris et al. (1986a and 1986b), found that a factor analysis was conducted in their original study. They found that the first three items loaded
together on one factor and the fourth one, the problematic one, loaded separately on its own factor. This gave the researcher insight that item four might need to be excluded.

Further statistical analysis confirmed this through examination of the inter-item correlation and adjusted alpha if the item was deleted. The first three items were found to be correlated with one another (correlation coefficients of 0.32, 0.48, and 0.46). The fourth item was not correlated greatly with any of the others (correlation coefficient = 0.07). Also, if item four was deleted, the adjusted alpha coefficient became 0.66. This alpha value was deemed acceptable by the researcher based on Nunnally’s criteria and previous use of the items by Morris et al. (1986a and 1986b). Therefore item four was dropped from the analysis.

In the reliability analysis of the construct perceived behavioral control in obtaining a prescription for HytrinR, there also were problems. The Cronbach’s Alpha of 0.32 indicates that the items used to measure this construct were not reliable. It is possible that the problem was not necessarily with the items, but that many of the respondents
were unfamiliar with the product Hytrin\textsuperscript{R}. All three groups, including the control and disease specific institutional ad group, were asked to respond to these items. Therefore, lack of knowledge of the product Hytrin\textsuperscript{R} could produce an unreliable measure of a multi-item construct. This problem, however, was corrected.

In Ajzen’s work measuring perceived behavioral control, he discussed the use of both multiple items and a single item to measure perceived behavioral control (Ajzen, 1991). Therefore, the researcher included both multiple item and single item measures for perceived behavioral control in obtaining a prescription for Hytrin\textsuperscript{R} and for obtaining a prostate exam in the research instrument. For the analysis to follow, perceived behavioral control for obtaining a prostate exam will be analyzed using a multiple item measure (Cronbach’s Alpha 0.72) and perceived behavioral control in obtaining a prescription for Hytrin\textsuperscript{R} will be analyzed using a single item measure.
TREATMENT AND CONTROL GROUPS

Study participants were randomly assigned to either one of the two treatment groups or the control group. From the original sample of 1093, a total of 296 usable responses was collected. The distribution of respondents among the three groups is presented in Table 2.

<table>
<thead>
<tr>
<th>Control Group</th>
<th>107</th>
<th>36.2%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease Specific Ad</td>
<td>96</td>
<td>32.4%</td>
</tr>
<tr>
<td>Hytrin(^R) Ad</td>
<td>93</td>
<td>31.4%</td>
</tr>
<tr>
<td>Total</td>
<td>296</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Table 2: Distribution of Respondents Among the Three Groups

Table 2 shows that approximately one-third of the respondents were distributed in each group.

The researcher also examined the equivalence of the respondents from each of the three groups by comparison of the demographic characteristics. Chi square analysis was conducted to determine if any of the three groups varied based on the demographics collected in the study. The
demographics collected were marital status, education level, residence, income, and age. Residence was defined as where the respondent lived with the range being from large city to rural. The results of these analyses are presented in Table 3.

<table>
<thead>
<tr>
<th>Demographic</th>
<th>n</th>
<th>Chi-square</th>
<th>DF</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marital status</td>
<td>282</td>
<td>11.69</td>
<td>8</td>
<td>0.17</td>
</tr>
<tr>
<td>Education level</td>
<td>281</td>
<td>17.16</td>
<td>14</td>
<td>0.25</td>
</tr>
<tr>
<td>Residence</td>
<td>281</td>
<td>17.24</td>
<td>12</td>
<td>0.14</td>
</tr>
<tr>
<td>Income</td>
<td>244</td>
<td>12.48</td>
<td>10</td>
<td>0.25</td>
</tr>
<tr>
<td>Age</td>
<td>283</td>
<td>3.24</td>
<td>6</td>
<td>0.79</td>
</tr>
</tbody>
</table>

**Table 3: Equivalence of the Groups Based on Demographics**

The results of Table 3 show that there were no significant differences among the three groups based on the demographics collected for the study. This reaffirms that the randomization of the study participants to one of the three groups did, in fact, yield equivalent groups based on the demographic information collected. The complete
The demographic composition of the study respondents is presented in Tables 4, 5, 6, 7, and 8.

<table>
<thead>
<tr>
<th></th>
<th>Control (n=101)</th>
<th>Institutional Ad (n=92)</th>
<th>Product Specific Ad (n=89)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MARRITAL STATUS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>93.0%</td>
<td>93.5%</td>
<td>91.0%</td>
</tr>
<tr>
<td>Divorced</td>
<td>4.0%</td>
<td>1.0%</td>
<td>2.2%</td>
</tr>
<tr>
<td>Separated</td>
<td>0.0%</td>
<td>0.0%</td>
<td>1.2%</td>
</tr>
<tr>
<td>Widowed</td>
<td>3.0%</td>
<td>2.2%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Never Married</td>
<td>0.0%</td>
<td>3.3%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Column Total</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

n = 282, Chi-Square = 11.69, DF = 8, and p-value = 0.17

**Table 4: Demographic Characteristics for Marital Status**
### Table 5: Demographic Characteristics for Education Level

<table>
<thead>
<tr>
<th>EDUCATION LEVEL</th>
<th>Control (n=101)</th>
<th>Institutional Ad (n=92)</th>
<th>Product Specific Ad (n=88)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elementary School</td>
<td>2.0%</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Some High School</td>
<td>17.0%</td>
<td>9.8%</td>
<td>5.7%</td>
</tr>
<tr>
<td>High School Diploma</td>
<td>34.0%</td>
<td>32.6%</td>
<td>41.0%</td>
</tr>
<tr>
<td>Some College</td>
<td>20.0%</td>
<td>20.7%</td>
<td>19.3%</td>
</tr>
<tr>
<td>2-Year College Degree</td>
<td>6.0%</td>
<td>4.3%</td>
<td>3.4%</td>
</tr>
<tr>
<td>4-Year College Degree</td>
<td>7.0%</td>
<td>18.5%</td>
<td>15.9%</td>
</tr>
<tr>
<td>Some Graduate Work</td>
<td>7.0%</td>
<td>4.3%</td>
<td>4.5%</td>
</tr>
<tr>
<td>Graduate Degree</td>
<td>8.0%</td>
<td>9.8%</td>
<td>10.2%</td>
</tr>
<tr>
<td>Column Total</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

n = 281, Chi-Square = 17.16, DF = 14 and p-value = 0.25

### Table 6: Demographic Characteristics for Residence

<table>
<thead>
<tr>
<th>RESIDENCE</th>
<th>Control (n=101)</th>
<th>Institutional Ad (n=91)</th>
<th>Product Specific Ad (n=89)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large City (over 100,000)</td>
<td>20.0%</td>
<td>30.8%</td>
<td>30.3%</td>
</tr>
<tr>
<td>City (50,000-100,000)</td>
<td>20.0%</td>
<td>14.3%</td>
<td>13.5%</td>
</tr>
<tr>
<td>Small City (10,000-49,999)</td>
<td>26.0%</td>
<td>27.4%</td>
<td>25.8%</td>
</tr>
<tr>
<td>Town (2,500-9,999)</td>
<td>15.0%</td>
<td>13.2%</td>
<td>5.6%</td>
</tr>
<tr>
<td>Small Town (under 2,500)</td>
<td>2.0%</td>
<td>5.5%</td>
<td>6.7%</td>
</tr>
<tr>
<td>Rural</td>
<td>18.0%</td>
<td>8.8%</td>
<td>17.9%</td>
</tr>
<tr>
<td>Column Total</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

n = 281, Chi-Square = 17.24, DF = 12, and p-value = 0.14
### Table 7: Demographic Characteristics for Income

<table>
<thead>
<tr>
<th>INCOME</th>
<th>Control (n=89)</th>
<th>Institutional Ad (n=78)</th>
<th>Product Specific Ad (n=77)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$0-$9,999</td>
<td>4.5%</td>
<td>1.3%</td>
<td>5.2%</td>
</tr>
<tr>
<td>$10,000-$19,999</td>
<td>11.2%</td>
<td>11.6%</td>
<td>18.2%</td>
</tr>
<tr>
<td>$20,000-$29,999</td>
<td>28.1%</td>
<td>25.6%</td>
<td>27.3%</td>
</tr>
<tr>
<td>$30,000-$39,999</td>
<td>24.7%</td>
<td>21.8%</td>
<td>9.0%</td>
</tr>
<tr>
<td>$40,000-$49,999</td>
<td>9.0%</td>
<td>17.9%</td>
<td>14.3%</td>
</tr>
<tr>
<td>$50,000 and above</td>
<td>22.5%</td>
<td>21.8%</td>
<td>26.0%</td>
</tr>
<tr>
<td>Column Total</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

n = 244, Chi-Square = 12.48, DF = 10, and p-value = 0.25

### Table 8: Demographic Characteristics for Age

<table>
<thead>
<tr>
<th>AGE</th>
<th>Control (n=102)</th>
<th>Institutional Ad (n=92)</th>
<th>Product Specific Ad (n=89)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 50 years</td>
<td>0.0%</td>
<td>1.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>50 to 59 years</td>
<td>0.0%</td>
<td>1.0%</td>
<td>1.0%</td>
</tr>
<tr>
<td>60 to 75 years</td>
<td>99.0%</td>
<td>97.0%</td>
<td>98.0%</td>
</tr>
<tr>
<td>76 years and older</td>
<td>1.0%</td>
<td>1.0%</td>
<td>1.0%</td>
</tr>
<tr>
<td>Column Total</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

n = 283, Chi-Square = 3.24, DF = 6, and p-value = 0.79
RESEARCH QUESTION 1
ADVERTISING EFFECT ON ATTITUDES

Hypothesis 1.1

There is a difference in the consumer’s attitude toward DTCA among the three treatment groups (control group, disease specific institutional advertisement group, and the product specific advertisement group).

Consumer attitudes toward DTCA were measured using a 14 item summated scale. One way analysis of variance was used to determine differences in attitudes among the three groups. The results are presented in Table 9.

<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>105</td>
<td>50.9</td>
<td>17-85</td>
<td>1.37</td>
</tr>
<tr>
<td>Institutional Ad</td>
<td>93</td>
<td>47.9</td>
<td>14-75</td>
<td>1.37</td>
</tr>
<tr>
<td>Product Specific Ad</td>
<td>91</td>
<td>48.6</td>
<td>22-84</td>
<td>1.39</td>
</tr>
</tbody>
</table>

n = 289, F Ratio = 1.39, DF = 288, and F Probability = 0.25

Table 9: Advertising’s Affect on Attitudes Toward DTCA
There was no statistically significance difference among the three groups regarding their overall attitudes toward DTCA. The interventions had no effect on respondents' attitudes toward DTCA. Therefore, Hypothesis 1.1 was not supported. One way analysis of variance also was conducted for each individual question in this section. Analysis of each individual question yielded no significant differences among the groups either. There were, however, some interesting descriptive findings when the attitudes toward DTCA were analyzed together for all three groups. Table 10 presents these findings. Scores of 5, 6, or 7 on the Likert-type scale comprised agreement and scores of 1, 2, and 3 comprised disagreement with the statements in the summary tables that follow.
** 34% of the respondents reported they would like to see more DTCA for prescription drugs.

** 66% of the respondents reported DTCA provides consumers with information they have a right to know.

** 63% of the respondents reported prescription drug information should come from a doctor or pharmacist.

** 17% of the respondents reported they could tell if an ad for a prescription drug was misleading.

** 54% of the respondents revealed that only a doctor can tell if an ad for a prescription drug is truthful or not.

** 40% of the respondents revealed that DTCA will benefit consumers.

** 38% of the respondents reported that prescription drugs should not be advertised to consumers.

** 61% of the respondents reported DTCA provides useful information to consumers.

** 16% of the respondents revealed that DTCA does not cause prescription drug prices to increase.

** 23% of the respondents reported that just because a prescription drug is advertised to consumers it’s safe.

** 11% of the respondents reported that patients can tell if a prescription drug should or should not be used.

** 59% of the respondents revealed that prescription drugs for serious medical problems should not be advertised to consumers.

** 27% of the respondents reported that DTCA is a reliable source of drug information.

** 43% of the respondents reported that the government should regulate DTCA.

Table 10: Respondents Attitudes Toward DTCA
The respondents reported that DTCA provides consumers with information they have a right to know (66%). This illustrates that consumers want more drug information, but other results indicate consumers may be hesitant to accept the validity of the information presented in DTCA. Only 27% felt that DTCA is a reliable source of drug information, 17% could tell if they were being misled by an ad, and 23% felt that just because a prescription drug is advertised it’s safe to use. These findings, along with the fact that only 34% would like to see more DTCA and 40% felt DTCA will benefit consumers, shows that this segment of the population is somewhat skeptical of the usefulness of DTCA. They may view DTCA as only a marketing tool used to sell more product by the pharmaceutical manufacturers and not an education tool designed to help patients seek appropriate treatment.
Hypothesis 1.2

There is a difference in the consumer’s attitude toward the product Hytrin® among the three treatment groups (control group, disease specific institutional advertisement group, and the product specific advertisement group).

Consumer attitudes toward the product Hytrin® were measured using a 13 item summated scale. One way analysis of variance was used to determine differences in attitudes among the three groups. The number of individuals in each group was relatively small, but the power (1 - β) was still 0.90 (Bratcher, Moran, and Zimmer, 1970). The results are presented in Table 11.

<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>29</td>
<td>66.1</td>
<td>52-86</td>
<td>1.43</td>
</tr>
<tr>
<td>Institutional Ad</td>
<td>18</td>
<td>60.8</td>
<td>40-85</td>
<td>2.99</td>
</tr>
<tr>
<td>Product Specific Ad</td>
<td>39</td>
<td>62.9</td>
<td>23-91</td>
<td>1.81</td>
</tr>
</tbody>
</table>

n = 86, F Ratio = 1.51, DF = 85, and F Probability = 0.23

Table 11: Attitudes Toward The Product Hytrin
Only individuals who had heard of Hytrin were asked to respond to this section of question regarding Hytrin. Those individuals who had never heard of Hytrin were asked to skip this set of questions. There was no statistically significance difference among the three groups regarding their overall attitudes toward Hytrin\textsuperscript{R}. The interventions had no effect on respondents' attitudes toward Hytrin\textsuperscript{R}. Therefore, Hypothesis 1.2 was not supported. One way analysis of variance also was conducted for each individual question in this section. Analysis of each individual question yielded no significant differences among the groups as well. There were, however, some interesting findings when the attitudes toward Hytrin\textsuperscript{R} were analyzed together for all three groups. Table 12 presents these findings.
** 67% were undecided about whether Hytrin\textsuperscript{R} is a safe drug.

** 79% were undecided about whether Hytrin\textsuperscript{R} would work better than other treatments for an enlarged prostate.

** 64% were undecided about whether Hytrin\textsuperscript{R} is effective in treating an enlarged prostate.

** 79% were undecided about Hytrin\textsuperscript{R} being the most successful way to treat an enlarged prostate.

** 48% responded they would feel comfortable asking their doctor to prescribe Hytrin\textsuperscript{R} for them if they developed an enlarged prostate while only 7% responded they would feel uncomfortable.

** 34% responded that the benefits of taking Hytrin\textsuperscript{R} outweighed the risks.

** 71% were undecided when asked about taking other drugs than Hytrin\textsuperscript{R} for an enlarged prostate.

** 82% responded they would use Hytrin\textsuperscript{R} if their doctor prescribed it for them.

** 84% reported they would ask their doctor for more information about Hytrin\textsuperscript{R}

** 90% reported they would ask their doctor’s opinion on Hytrin.

** 71% reported an enlarged prostate is a serious disease.

** 13% reported it is not worth the risk of side effects of drugs to treat an enlarged prostate.

**Table 12: Respondents Attitudes Toward Hytrin**
Individuals who responded to the questions about Hytrin® had heard about its use to treat an enlarged prostate in the past. Abbott Laboratories has conducted various advertising campaigns to promote the use of Hytrin® for an enlarged prostate in the past. This could account for patient’s knowledge of the drug in the control and institutional ad groups. Family and friends who have taken the drug could also have been a past source of information. The study did not measure where the patient’s had heard of Hytrin® from outside from our advertisement sent to the product specific treatment group. Finally, patients could have taken Hytrin® in the past or were currently taking Hytrin®. Analysis of past and current use of Hytrin®, however, was not statistically different among the three groups.

From the results presented in Table 12, individuals who have heard of the drug still are unsure about its safety and effectiveness in treating an enlarged prostate. Seventy-nine percent were unsure about how Hytrin® compared in effectiveness to other treatments and 67% were unsure about the drug’s safety. However, 84% would ask their doctor
about for more information about Hytrin and 90% would ask their doctor's opinion. This illustrates that DTCA may not have the power to affect attitudes toward a product, but may promote information seeking behavior, increase involvement, and increase communication between the patient and the doctor. The patient then still relies on the doctor for knowledge about prescription drug safety and effectiveness, at least for this population.

**Hypothesis 1.3**

There is a difference in the consumer’s attitude toward asking the physician for a prescription for a specific product among the three treatment groups (control group, disease specific institutional advertisement group, and the product specific advertisement group).

Consumer attitudes toward asking the physician for a prescription for a specific product were measured using a three item summed scale. One way analysis of variance was
used to determine differences in attitudes among the three groups. The results are presented in Table 13.

<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>105</td>
<td>7.2</td>
<td>3-20</td>
<td>0.35</td>
</tr>
<tr>
<td>Institutional Ad</td>
<td>95</td>
<td>6.8</td>
<td>3-19</td>
<td>0.37</td>
</tr>
<tr>
<td>Product Specific Ad</td>
<td>92</td>
<td>7.1</td>
<td>3-17</td>
<td>0.37</td>
</tr>
</tbody>
</table>

n = 292, F Ratio = 0.39, DF = 291, and F Probability = 0.68

**Table 13: Attitudes Toward Asking for a Prescription**

There was no statistically significance difference among the three groups regarding their overall attitudes toward asking the physician for a prescription for a specific product. The interventions had no effect on respondents attitudes toward asking the physician for a prescription for a specific product. Therefore, Hypothesis 1.3 was not supported. One way analysis of variance was also conducted for each individual question in this section. Analysis of each individual question yielded no significant differences between the groups as well. There were,
however, some interesting findings when the attitudes toward Hytrin were analyzed together for all three groups. Table 14 presents these findings.

** 15% of the respondents would be upset with their doctor if he/she refused their request for a prescription for a specific drug.

** 9% of the respondents would go to another doctor with their request if their own doctor refused a request to prescribe a specific drug.

** 86% would follow their doctor’s advice if he/she refused their request for a prescription for a specific drug. (This question was not included in the summated attitude score.)

** 18% would be upset with themselves if their doctor refused their request for a prescription for a specific drug.

Table 14: Respondents Attitudes Toward Asking for a Prescription for a Specific Product

These results indicate that for this particular patient population individuals are not quite ready to exert some authority over physician’s prescribing habits. These respondents still trust their physician’s judgment no matter what their own personal attitudes towards a prescription
product may be. These results do, however, illustrate that patients would not be upset with themselves for asking even if a physician failed to grant a request. This shows that patients may not be afraid of the consequences of asking their physician for a prescription for a specific product. This may be an important step in patient-physician communication and relations.

The advertisements in this study presumably were designed to try to affect patient's attitudes based on content analysis of the wording in the text. From the results stated above, the advertisements did not significantly change a patient’s attitudes either positively or negatively about the DTCA, Hytrin®, or asking the physician for a prescription for a specific product. This may suggest that DTCA directed at changing attitudes may be ineffective in its present form.
RESEARCH QUESTION 2  EFFECTS ON SUBJECTIVE NORMS, PERCEIVED BEHAVIORAL CONTROL, BEHAVIORAL INTENT, & BEHAVIOR

Hypothesis 2.1

There is a difference in the consumer's subjective norms among the three treatment groups (control group, disease specific institutional advertisement group, and the product specific advertisement group).

The subjective norms of the respondents were calculated as the product of four motivation to comply statements and four corresponding normative belief statements. The four products (scores) were then summed together. This gave a summated score of subjective norms. One way analysis of variance was used to determine differences in subjective norms among the three groups. The results are presented in Tables 15 and 16.
### Table 15: Subjective Norms Toward Obtaining a Prostate Exam

<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>98</td>
<td>110.5</td>
<td>20-196</td>
<td>4.35</td>
</tr>
<tr>
<td>Institutional Ad</td>
<td>91</td>
<td>100.5</td>
<td>7-196</td>
<td>4.17</td>
</tr>
<tr>
<td>Product Specific Ad</td>
<td>80</td>
<td>108.1</td>
<td>19-196</td>
<td>4.67</td>
</tr>
</tbody>
</table>

n = 269,  F Ratio = 1.47, DF = 268, and F Probability = 0.23

### Table 16: Subjective Norms Toward the Product Hytrin

<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>95</td>
<td>71.1</td>
<td>10-169</td>
<td>3.16</td>
</tr>
<tr>
<td>Institutional Ad</td>
<td>84</td>
<td>71.2</td>
<td>7-163</td>
<td>3.63</td>
</tr>
<tr>
<td>Product Specific Ad</td>
<td>79</td>
<td>74.5</td>
<td>13-124</td>
<td>3.11</td>
</tr>
</tbody>
</table>

n = 258,  F Ratio = 0.34, DF = 257, and F Probability = 0.71

There was no statistically significance difference among the three groups regarding their overall subjective norms toward obtaining a prostate exam or toward the product Hytrin®. The interventions had no effect on respondents' attitudes toward asking the physician for a prescription for
a specific product. Therefore, Hypothesis 2.1 was not supported. One way analysis of variance also was conducted for each individual question in this section. Analysis of each individual question yielded no significant differences between the groups as well. There were, however, some interesting findings when the subjective norms were analyzed together for all three groups. Table 17 presents these findings.

** 79% of the respondents reported their doctor thinks they should have a prostate exam compared to 61% for family, 42% for good friends, and 24% for their pharmacist.

** 13% of the respondents reported their doctor thinks they should ask for a prescription for Hytrin if they developed an enlarged prostate compared to 8% for family, 6% for good friends, and 9% for their pharmacist.

** 94% of the respondents reported they want to do what their doctor thinks they should do compared with 74% for family, 34% for good friends, 35% for their pharmacist.

Table 17: Respondents Subjective Norms
The results show that the patient's physician and family have a great deal of influence on what the patient believes he should do. Therefore, DTCA using appeals of subjective norms to affect behavior should concentrate on using the patient's doctor and family as referent groups. These seem to be the two groups that have the most influence with patients and might have the most success in changing behavior. The advertisements used in the study did not contain any appeals regarding subjective norms. Therefore it is not surprising that the subjective norms between the three groups were not different.

**Hypothesis 2.2**

There is a difference in the consumer's perceived behavioral control among the three treatment groups (control group, disease specific institutional advertisement group, and the product specific advertisement group).

Perceived behavioral control can be measured using a multi-item or single item measure (Ajzen, 1991). For this
study, both single and multi-item measures were used. For the perceived behavioral control in convincing a physician to give the patient a prostate exam, a multi-item (4 question) measure was found to be reliable (alpha = 0.72) and was used for the analysis. These four items yielded a summated score. The analysis also was conducted using a single-item measure.

For the perceived behavioral control in convincing a physician to write a prescription for Hytrin®, a multi-item measure was not found to be reliable (alpha = 0.32). Therefore a single-item measure was used in the analysis. One way analysis of variance was used to determine differences in perceived behavioral control among the three groups. The results are presented in Tables 18, 19, and 20.

<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>104</td>
<td>23.2</td>
<td>7-28</td>
<td>0.49</td>
</tr>
<tr>
<td>Institutional Ad</td>
<td>89</td>
<td>23.9</td>
<td>10-28</td>
<td>0.45</td>
</tr>
<tr>
<td>Product Specific Ad</td>
<td>82</td>
<td>23.0</td>
<td>14-28</td>
<td>0.45</td>
</tr>
</tbody>
</table>

n = 275, F Ratio = 0.93, DF = 274, and F Probability = 0.39

Table 18: Perceived Behavioral Control in Obtaining a Prostate Exam (Multi-item Measure)
<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>102</td>
<td>1.18</td>
<td>1-7</td>
<td>0.12</td>
</tr>
<tr>
<td>Institutional Ad</td>
<td>88</td>
<td>1.63</td>
<td>1-7</td>
<td>0.17</td>
</tr>
<tr>
<td>Product Specific Ad</td>
<td>84</td>
<td>1.58</td>
<td>1-7</td>
<td>0.17</td>
</tr>
</tbody>
</table>

n = 274, F Ratio = 6.58, DF = 273, and F Probability = .002

Table 19: Perceived Behavioral Control in Obtaining a Prostate Exam (Single-item Measure)

There was no statistically significance difference among the three groups regarding their perceived behavioral control in obtaining a prostate exam using the multi-item measure. Therefore, Hypothesis 2.2 was not supported for the multi-item measure. One way analysis of variance also was conducted for each individual question in this section. Analysis of each individual question yielded no significant differences among the groups as well. However, for the single item measure, there was a statistically significant difference among the three groups regarding their perceived behavioral control in obtaining a prostate exam.

A post hoc analysis was conducted. A Least Significant Difference (LSD) test indicated significant differences
between the control group and disease specific institutional ad group and between the control group and product specific ad group. A more conservative test, Scheffe’s Test, indicated significant differences only between the control group and the product specific advertisement. Therefore, Hypothesis 2.2 was supported for the single-item measure.

These findings create a dilemma for the researcher. Research in the field of perceived behavioral control is still in a developmental stage. The construct was first introduced in 1991 by Ajzen. Therefore research into which method, a single-item or multi-item measure, is the best remains to be determined. Perceived behavioral control is believed to contain four parts used to measure control in a specific behavioral situations according to Ajzen. These are ability, motivation, time, and need of assistance. In our multi-item measure an item was used to measure each part. This yielded non-statistically significant results among the three groups.

However, our single-item measure contained the actual words, “I would have very little control........” in the question. This item was a direct measure of how much
control patients felt they had. Therefore, this may be a better measure of perceived behavioral control than the multi-item measure for this given behavior. This also suggests that there may be other parts to a multi-item measure of perceived behavioral control that have yet to be identified.

<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>100</td>
<td>3.87</td>
<td>1-7</td>
<td>0.17</td>
</tr>
<tr>
<td>Institutional Ad</td>
<td>85</td>
<td>4.21</td>
<td>1-7</td>
<td>0.20</td>
</tr>
<tr>
<td>Product Specific Ad</td>
<td>82</td>
<td>3.92</td>
<td>1-7</td>
<td>0.17</td>
</tr>
</tbody>
</table>

n = 267, F Ratio = 0.99, DF = 266, and F Probability = 0.37

**Table 20: Perceived Behavioral Control in Convincing a Physician to Write a Prescription for Hytrin (Single-item)**

There was no statistically significance difference among the three groups regarding their perceived behavioral control toward convincing their physician to write a prescription for the product Hytrin\(^\text{R}\). The interventions had no effect on respondents perceived behavioral control toward convincing their physician to write a prescription for
Hytrin®. Therefore, this part of Hypothesis 2.2 was not supported. When the respondents were analyzed as a whole, there were some interesting findings. Table 21 presents these findings.

** 78% of the respondents reported they had the ability to convince their doctor to give them a prostate exam.

** 69% of the respondents reported they were motivated to ask their doctor for a prostate exam.

** 89% of the respondents revealed they had the time to see their doctor for a prostate exam.

** 5% of the respondents reported they would need assistance in convincing their doctor to give them a prostate exam.

** 19% of the respondents reported they have the ability to convince their doctor to write a prescription for Hytrin® if they wanted to.

** 23% of the respondents revealed they would be motivated to ask their doctor to write a prescription for Hytrin® if a prostate exam showed an enlarged prostate.

** 89% of the respondents reported they had the time to see their doctor and discuss treating an enlarged prostate.

** 55% of the respondents reported that they were not sure if they would need assistance in convincing their doctor to write a prescription for Hytrin®.

**Table 21: Respondents Perceived Behavioral Control**
These results illustrate different levels of perceived behavioral control for different behaviors. The perceived behavioral control in obtaining a prostate exam is much higher than for the perceived behavioral control in convincing a physician to write a prescription for Hytrin®. This reinforces the theory that an individual's perceived control may change among different behaviors. As Ajzen stated, the amount of behavioral control is situation specific and may change between different behaviors (Ajzen, 1991). These findings support that conclusion.

The only similarity between these two behaviors regarding perceived behavioral control was the time characteristic. Since the two behaviors require essentially the same time commitment, going to visit the doctor, we would expect the results of this component of perceived behavioral control to be similar.
Hypothesis 2.3

There is a difference in the consumer's behavioral intent to ask the physician for a prostate exam among the three treatment groups (control group, disease specific institutional advertisement group, and the product specific advertisement group).

Behavioral intent in asking for prostate exam was measured using 2 individual questions. These questions were not summed to create a summated score. Questions b and c in section five of the questionnaire contained different levels of effort needed by the patient to obtain a prostate exam. The first question (question b) asked the respondent if he intended to ask his doctor to give him a prostate exam at his next scheduled appointment. The next question (question c) required a much stronger response by the patient. This question asked the respondent if he intended to make a special appointment to see his doctor to give him a prostate exam. One way analysis of variance was used to determine
differences in behavioral intent among the three groups.

The results are presented in Tables 22 and 23.

<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>100</td>
<td>4.72</td>
<td>1-7</td>
<td>0.20</td>
</tr>
<tr>
<td>Institutional Ad</td>
<td>84</td>
<td>4.53</td>
<td>1-7</td>
<td>0.24</td>
</tr>
<tr>
<td>Product Specific Ad</td>
<td>80</td>
<td>4.78</td>
<td>1-7</td>
<td>0.21</td>
</tr>
</tbody>
</table>

n = 264, F Ratio = 0.32, DF = 263, and F Probability = 0.72

Table 22: Intent of Asking the Physician for a Prostate Exam at the Next Scheduled Appointment

<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>99</td>
<td>3.74</td>
<td>1-7</td>
<td>0.22</td>
</tr>
<tr>
<td>Institutional Ad</td>
<td>83</td>
<td>3.52</td>
<td>1-7</td>
<td>0.24</td>
</tr>
<tr>
<td>Product Specific Ad</td>
<td>80</td>
<td>3.71</td>
<td>1-7</td>
<td>0.21</td>
</tr>
</tbody>
</table>

n = 262, F Ratio = 0.29, DF = 261, and F Probability = 0.75

Table 23: Intent of Making a Special Appointment to See the Physician for a Prostate Exam
There was no statistically significance difference among the three groups regarding their behavioral intent in obtaining a prostate exam at either level of effort. The scores were, however, slightly lower for the behavioral intent that require a stronger effort (making a special appointment for a prostate exam). The interventions had no effect on respondents behavioral intent in obtaining a prostate exam. Therefore, Hypothesis 2.3 was not supported.

Respondents also were asked their intentions on asking their pharmacist if they should have a prostate exam. This question was added to determine if patients wanted the pharmacist to play a role counseling and helping the patient seek treatment for BPH and was purely exploratory in nature. As expected, one-way analysis of variance yielded no significant differences among the three groups (p = 0.43). The mean for the control group was 2.13, the mean for the institutional ad group was 1.95 and the mean for the product specific ad group was 2.28. These low scores were expected since none of the interventions even mentioned pharmacist intervention in this disease state. But the researcher wanted to know if the pharmacist had a role to play in
treating this disease other than just filling the prescription for treatment.

When all the respondents were analyzed together, 60% strongly disagreed that they intend to talk to their pharmacist about whether to get a prostate exam or not. In fact, only 5% indicated they would talk to their pharmacist about whether to get a prostate exam or not. These results indicate that prostate problems is not an area that patients feel comfortable discussing with their pharmacist. This represents a challenge to pharmacists to increase their involvement in providing pharmaceutical care to patients with BPH.

**Hypothesis 2.4**

There is a difference in the consumer’s actual behavior of obtaining a prostate exam among the three treatment groups (control group, disease specific institutional advertisement group, and the product specific advertisement group).
Respondents were asked to base their answers to these questions only for behaviors over the last five months. Five months was the time period between when the first advertisement was sent and when they received the questionnaire asking these questions. Respondents were asked if they had been to the doctor in the last five months and if they had had a prostate exam in the last five months. The prostate exam question was disguised among 4 other diagnostic tests so the respondents would not derive the true intent of what the researcher was measuring. Differences between the groups were determined using Chi-square analysis. The results of this analysis are presented in Tables 24 and 25.
### EXPERIMENTAL GROUP

<table>
<thead>
<tr>
<th></th>
<th>Control (n=88)</th>
<th>Institutional Ad (n=85)</th>
<th>Product Specific Ad (n=77)</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>88.6%</td>
<td>92.9%</td>
<td>85.7%</td>
</tr>
<tr>
<td>NO</td>
<td>11.4%</td>
<td>7.1%</td>
<td>14.3%</td>
</tr>
<tr>
<td>COLUMN TOTAL</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

\[ n = 250, \text{ Chi-Square} = 2.24, \text{ DF} = 2, \text{ and p-value} = 0.33 \]

**Table 24: Doctor Visit in the Last Five Months**

### EXPERIMENTAL GROUP

<table>
<thead>
<tr>
<th></th>
<th>Control (n=88)</th>
<th>Institutional Ad (n=85)</th>
<th>Product Specific Ad (n=77)</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>53.4%</td>
<td>64.7%</td>
<td>53.2%</td>
</tr>
<tr>
<td>NO</td>
<td>46.6%</td>
<td>35.3%</td>
<td>46.8%</td>
</tr>
<tr>
<td>COLUMN TOTAL</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

\[ n = 250, \text{ Chi-Square} = 2.96, \text{ DF} = 2, \text{ and p-value} = 0.23 \]

**Table 25: Prostate Test in the Last Five Months**
The results indicate there is no statistically significant difference among the treatment groups and whether the individual has been to the doctor or has had a prostate exam during the study period. This shows that neither the disease specific institutional advertisement nor the product specific Hytrin® advertisement had an affect on the respondent’s behavior of going to the doctor or getting a prostate exam. Therefore hypothesis 2.4 was not supported.

A prostate exam can be an unpleasant experience. Therefore, an intervention should be very persuasive in order for men to request such an unpleasant procedure. This probably would require several repeated exposures to a multitude of messages to change the attitudes of men regarding the importance of this exam. The 57% who received a prostate exam in our study probably did so because some physicians view it as a standard of care for men over the age of 55.

The reason a doctor’s visit was measured is because the respondent may have made an appointment to see his doctor to ask for a prostate exam and the doctor refused. The
interventions would have worked, but the results would not be captured by the prostate exam question. The doctor could have refused because he/she felt it was unnecessary or decided to conduct a PSA blood test to determine if the prostate was enlarged. If this was the case, a significant number of respondents would have visited their doctor in the institutional ad group and the product specific ad group. However, no statistically significance difference was observed among the three groups.

Hypothesis 2.5

There is a difference in the consumer’s behavioral intent in asking for a prescription for Hytrin® if a prostate exam shows the patient’s prostate was enlarged among the three treatment groups (control group, disease specific institutional advertisement group, and the product specific advertisement group).
Behavioral intent in asking for a prescription for Hytrin\(^R\) was measured using a single question. The question asked the respondent if a prostate exam showed his prostate was enlarged and he needed treatment, would he ask his doctor for a prescription for Hytrin\(^R\). One way analysis of variance was used to determine differences in behavioral intent among the three groups. The results are presented in Table 26.

<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>100</td>
<td>3.92</td>
<td>1-7</td>
<td>0.16</td>
</tr>
<tr>
<td>Institutional Ad</td>
<td>83</td>
<td>3.63</td>
<td>1-7</td>
<td>0.18</td>
</tr>
<tr>
<td>Product Specific Ad</td>
<td>80</td>
<td>3.89</td>
<td>1-7</td>
<td>0.15</td>
</tr>
</tbody>
</table>

n = 263, F Ratio = 0.83, DF = 262, and F Probability = 0.44

Table 26: Intent of Asking the Physician for a Prescription for the Product Hytrin

There was no statistically significance difference among the three groups regarding their behavioral intent in asking their physician for a prescription for Hytrin\(^R\). The
interventions had no effect on respondents behavioral intent in asking for a prescription for HytrinR if treatment was needed. Therefore, Hypothesis 2.5 was not supported. Interestingly enough behavioral intention for all three groups was slightly negative regarding asking for HytrinR if treatment was needed.

Hypothesis 2.6

There is a difference in the consumer’s actual behavior of obtaining prescription for HytrinR among the three treatment groups (control group, disease specific institutional advertisement group, and the product specific advertisement group).

Respondents were asked to base their answers to prescription drug usage only for new prescriptions obtained within the last five months. Five months was time period between when the first advertisement was sent and when they received the questionnaire asking these questions.
Respondents were asked if they had had a new prescription filled for any of the listed products within the last five months.

At that time, there were three products approved to treat BPH. These were Hytrin\textsuperscript{R}, Cardura\textsuperscript{R}, and Proscar\textsuperscript{R}. The other two products, Cardura\textsuperscript{R} and Proscar\textsuperscript{R}, were included in case the physician chose another drug for therapy even after the patient asked for Hytrin. By measuring all three drugs, this may show the intervention was still somewhat successful in changing behaviors, but the physician just chose a different product.

These products were disguised among 3 other popular prescription drug products (Zantac\textsuperscript{R}, Penicillin, and Vasotec\textsuperscript{R}). This was done so the respondents would not derive the true intent of what the researcher was measuring. Differences among the groups were determined using Chi-square analysis. The results of this analysis are presented in Table 27.
EXPERIMENTAL GROUP

<table>
<thead>
<tr>
<th></th>
<th>Control (n=88)</th>
<th>Institutional Ad (n=85)</th>
<th>Product Specific Ad (n=77)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hytrin</td>
<td>6.8%</td>
<td>7.0%</td>
<td>10.4%</td>
</tr>
<tr>
<td>Cardura</td>
<td>3.4%</td>
<td>2.4%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Proscar</td>
<td>2.3%</td>
<td>0.0%</td>
<td>2.6%</td>
</tr>
<tr>
<td>Hytrin &amp; Proscar</td>
<td>0.0%</td>
<td>1.2%</td>
<td>0.0%</td>
</tr>
<tr>
<td>None</td>
<td>87.5%</td>
<td>89.4%</td>
<td>87.0%</td>
</tr>
<tr>
<td>Column Total</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

n = 250, Chi-Square = 7.32, DF = 8, and p-value = 0.50

Table 27: Patients with New Prescriptions (last 5 months)

The results indicate there is no statistically significant difference among the treatment groups and whether an individual received a prescription for one of three products used to treat BPH during the study period. This shows that neither the disease specific institutional advertisement nor the product specific Hytrin® advertisement had an affect on the respondent’s final behavior of obtaining a prescription for one of three products used to treat BPH. Therefore Hypothesis 2.6 was not supported. Further Chi-square analysis was conducted to determine the
differences among the groups of just those individuals who received a prescription for Hytrin\textsuperscript{R}. Respondents were coded as either received a new prescription for Hytrin\textsuperscript{R} or not. The results are presented in Table 28.

\begin{center}
\begin{tabular}{lccc}
\hline
 & Control & Institutional Ad & Product Specific Ad \\
(n=88) & (n=85) & (n=77) \\
\hline
YES & 6.8\% & 8.2\% & 10.4\% \\
NO & 93.2\% & 91.8\% & 89.6\% \\
COLUMN TOTAL & 100.0\% & 100.0\% & 100.0\% \\
\hline
\end{tabular}
\end{center}

\textit{n = 250, Chi-Square = 0.69, DF = 2, and p-value = 0.71}

\textbf{Table 28: Patients Who Received a Prescription for Hytrin} \textsuperscript{R}

These results also indicate there is no statistically significant difference among the treatment groups and whether an individual received a prescription for Hytrin\textsuperscript{R} during the study period. This shows that neither the disease specific institutional advertisement nor the product specific Hytrin\textsuperscript{R} advertisement had an affect on the
respondent's final behavior of obtaining a prescription Hytrin\textsuperscript{R}. Therefore Hypothesis 2.6 again was not supported. Even further Chi-square analysis was conducted to determine the differences among the groups of those individuals who received a prescription for either Hytrin\textsuperscript{R}, Cardura\textsuperscript{R}, or Proscar\textsuperscript{R}. Respondents were coded as either received a new prescription for one of three or not. The results are presented in Table 29.

<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>Control (n=88)</th>
<th>Institutional Ad (n=85)</th>
<th>Product Specific Ad (n=77)</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>12.5%</td>
<td>10.6%</td>
<td>13.0%</td>
</tr>
<tr>
<td>NO</td>
<td>87.5%</td>
<td>89.4%</td>
<td>87.0%</td>
</tr>
<tr>
<td>COLUMN TOTAL</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

n = 250, Chi-Square = 0.25, DF = 2, and p-value = 0.88

Table 29: Patients Who Received a Prescription for One of Three Prescription Drugs - Hytrin, Cardura, or Proscar
Again, these results also indicate there is no statistically significant difference among the treatment groups and whether an individual received a prescription for any prescription drug approved for the treatment of BPH during the study period. This also demonstrates that neither the disease specific institutional advertisement nor the product specific Hytrin\textsuperscript{R} advertisement had an affect on the respondent’s final behavior of obtaining a prescription to treat BPH. Therefore Hypothesis 2.6 again was not supported.

Further analysis showed that only five study respondents actually received a new prescription for Hytrin who had previously not been treated with the drug in the past. Two were in the control group and three were in product specific Hytrin\textsuperscript{R} advertisement group. Chi-square analysis ($p = 0.66$) determined that this was not statistically significant. This finding does not support Hypothesis 2.6 either.
Other Measures of Effectiveness

There was, however, some indication of the intervention's effectiveness. Respondents were asked if they had ever heard of the drug Hytrin® which is used to treat an enlarged prostate. The question specifically mentioned enlarged prostate since Hytrin® is also used for hypertension. Respondents answered either yes or no. The results of this question were analyzed using Chi-square analysis among the three treatment groups. These results are presented in Table 30.

<table>
<thead>
<tr>
<th>Experimental Group</th>
<th>Control (n=102)</th>
<th>Institutional Ad (n=94)</th>
<th>Product Specific Ad (n=90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>18.6%</td>
<td>10.6%</td>
<td>37.8%</td>
</tr>
<tr>
<td>NO</td>
<td>81.4%</td>
<td>89.4%</td>
<td>62.2%</td>
</tr>
<tr>
<td>COLUMN TOTAL</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

n = 286, Chi-Square = 20.78, DF = 2, and p-value = 0.00003

Table 30: Patients Who Have Heard of Hytrin to Treat BPH
There is a significant difference among the treatment groups and whether or not they had heard of Hytrin$^\text{R}$ to treat BPH. The treatment group that received the ads for Hytrin$^\text{R}$ had a higher recall of having heard of the drug to treat BPH. By examining within group percentages, 38% of the treatment group respondents that received ads for Hytrin$^\text{R}$ recalled hearing of Hytrin$^\text{R}$ to treat BPH compared with only 19% of the respondents for the control group and 11% of the respondents for the institutional advertisement group. This may illustrate that the product specific ads for Hytrin$^\text{R}$ increased patient recall of the product even if it did not affect attitudes or subjective norms. A stronger intervention or more repetition may have lead to a change in attitudes which in turn may affect behavioral intent and possibly actual behavior.

Also, the respondents were asked if they had seen any advertisements for Hytrin$^\text{R}$ in the last 3 months. Other prescription drugs such as Proscar$^\text{R}$, Glucotrol$^\text{R}$, and Lasix$^\text{R}$ were also included to help disguise the intent of the question. Respondents were asked to circle all the drugs they had seen advertised. The results were analyzed using
Chi-square analysis between the three treatment groups. These results are presented in Table 31.

<table>
<thead>
<tr>
<th></th>
<th>Control (n=103)</th>
<th>Institutional Ad (n=88)</th>
<th>Product Specific Ad (n=84)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hytrin</td>
<td>3.9%</td>
<td>4.5%</td>
<td>16.7%</td>
</tr>
<tr>
<td>Proscar</td>
<td>18.4%</td>
<td>26.2%</td>
<td>20.2%</td>
</tr>
<tr>
<td>None</td>
<td>70.9%</td>
<td>63.6%</td>
<td>46.4%</td>
</tr>
<tr>
<td>Hytrin &amp; Proscar</td>
<td>6.8%</td>
<td>5.7%</td>
<td>16.7%</td>
</tr>
</tbody>
</table>

n = 275, Chi-Square = 24.15, DF = 6, and p-value = 0.00049

**Table 31: Respondents Who Had Seen an Advertisement**

There is a significant difference among the treatment groups regarding whether the respondent had seen an ad for Hytrin² or not. By collapsing the first (Hytrin²) and last (Hytrin¹ and Proscar²) categories, the following percentages are obtained: in the control group 10.7%, institutional ad group 10.2%, and in the product specific (Hytrin² ad) group 33.4% of the total recall seeing an ad for Hytrin¹. This
again demonstrates a proxy measure of effectiveness. Another way to examine it is using this method. Of the 84 respondents to this question from the product specific group, 28 (33.4%) recalled seeing an ad for Hytrin® compared with approximately 10% from each of the other two treatment groups. Again the intervention did increase recall of the product.

RESEARCH QUESTION 3
RELATIONSHIPS BETWEEN THE FIVE INDEPENDENT VARIABLES

Hypothesis 3.1

There are relationships between the five independent variables in the study model (attitude towards DTCA, attitude toward the product Hytrin®, attitude toward asking the physician for a prescription for a specific product, subjective norms, and perceived behavioral control).
There were five independent variables per model. The two models tested in this study were the same overall, but with different specific behavioral intents and behaviors. For the first model, the behavioral intent and behavior were related to obtaining a prostate exam and the second was related to obtaining a prescription for Hytrin\textsuperscript{R}. The three attitudes components are the same for both models, but the subjective norms and perceived behavioral control measures change for each model. Therefore there are seven independent variables total, but only five per model.

Correlation analysis was conducted to determine the relationships between the independent variables in the model. Pearson’s Product Moment Correlations were calculated for each pair of independent variables. Correlations of 0.30 were observed to be weak relationships between variables, 0.50 moderate relationships, and 0.70 or greater to be strong relationships. The results are presented in Tables 32 and 33.
<table>
<thead>
<tr>
<th></th>
<th>DTCA</th>
<th>HYTRIN</th>
<th>PHYSICIAN</th>
<th>SUBNORM</th>
<th>PBC</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTCA</td>
<td>0.06</td>
<td>0.17</td>
<td>0.10</td>
<td>0.06</td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=.60</td>
<td>p=.01</td>
<td>p=.10</td>
<td>p=.34</td>
<td></td>
</tr>
<tr>
<td>HYTRIN</td>
<td>0.06</td>
<td>-0.01</td>
<td>0.18</td>
<td>0.05</td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=.60</td>
<td>p=.97</td>
<td>p=.11</td>
<td>p=.66</td>
<td></td>
</tr>
<tr>
<td>PHYS</td>
<td>0.17</td>
<td>-0.01</td>
<td></td>
<td>0.06</td>
<td>-0.11</td>
</tr>
<tr>
<td></td>
<td>p=.01</td>
<td>p=.97</td>
<td></td>
<td>p=.32</td>
<td>p=.08</td>
</tr>
<tr>
<td>SUBNORM</td>
<td>0.10</td>
<td>0.18</td>
<td>0.06</td>
<td></td>
<td>0.41</td>
</tr>
<tr>
<td></td>
<td>p=.10</td>
<td>p=.11</td>
<td>p=.32</td>
<td></td>
<td>p=.00</td>
</tr>
<tr>
<td>PBC</td>
<td>0.06</td>
<td>0.05</td>
<td>-0.11</td>
<td>0.41</td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=.34</td>
<td>p=.66</td>
<td>p=.08</td>
<td></td>
<td>p=.00</td>
</tr>
</tbody>
</table>

DTCA = Attitude toward direct-to-consumer advertising  
HYTRIN = Attitude toward the product Hytrin®  
PHYS = Attitude toward asking the physician for a prescription for a specific product  
SUBNORM = Subjective norms in obtaining a prostate exam  
PBC = Perceived behavioral control in obtaining a prostate exam

Table 32: Correlations Between Independent Variables in the Model Testing Behavioral Intent in Obtaining a Prostate Exam
<table>
<thead>
<tr>
<th></th>
<th>DTCA</th>
<th>HYTRIN</th>
<th>PHYSICIAN</th>
<th>SUBNORM</th>
<th>PBC</th>
</tr>
</thead>
<tbody>
<tr>
<td>DTCA</td>
<td>0.06</td>
<td>0.17</td>
<td>0.06</td>
<td>-0.10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=.60</td>
<td>p=.01</td>
<td>p=.32</td>
<td>p=.11</td>
<td></td>
</tr>
<tr>
<td>HYTRIN</td>
<td>0.06</td>
<td>-0.01</td>
<td>0.29</td>
<td>0.06</td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=.60</td>
<td>p=.97</td>
<td>p=.01</td>
<td>p=.60</td>
<td></td>
</tr>
<tr>
<td>PHYS</td>
<td>0.17</td>
<td>-0.01</td>
<td></td>
<td>0.12</td>
<td>-0.11</td>
</tr>
<tr>
<td></td>
<td>p=.01</td>
<td>p=.97</td>
<td></td>
<td>p=.07</td>
<td>p=.07</td>
</tr>
<tr>
<td>SUBNORM</td>
<td>0.06</td>
<td>0.29</td>
<td>0.12</td>
<td></td>
<td>-0.01</td>
</tr>
<tr>
<td></td>
<td>p=.32</td>
<td>p=.01</td>
<td>p=.07</td>
<td></td>
<td>p=.88</td>
</tr>
<tr>
<td>PBC</td>
<td>-0.10</td>
<td>0.06</td>
<td>-0.11</td>
<td>-0.01</td>
<td></td>
</tr>
<tr>
<td></td>
<td>p=.11</td>
<td>p=.60</td>
<td>p=.07</td>
<td></td>
<td>p=.88</td>
</tr>
</tbody>
</table>

DTCA = Attitude toward direct-to-consumer advertising
HYTRIN = Attitude toward the product Hytrin®
PHYS = Attitude toward asking the physician for a prescription for a specific product
SUBNORM = Subjective norms in obtaining a prescription for Hytrin®
PBC = Perceived behavioral control in obtaining a prescription for Hytrin®

Table 33: Correlations Between Independent Variables in the Model for Obtaining a Prescription for the Product Hytrin®
None of the independent variables in the model were strongly associated with one another. However, two of the independent variables, subjective norms and perceived behavioral control in obtaining a prostate exam (0.41) and attitude toward the product Hytrin\textsuperscript{R} and subjective norms in obtaining a prescription for Hytrin\textsuperscript{R} (0.29) exhibited a weak or limited degree of association between the two variables. This analysis showed that the five variables for each model were not strongly related to one another. Therefore, Hypothesis 3.1 was not supported.

This provides some evidence that in our model there were no single direction or bi-directional arrows between the independent variables. No interrelationships of any appreciable strength were found in the above correlation analysis. This analysis also verified the absence of multicollinearity of the independent variables used in the model. Each item is measuring something unique.
RESEARCH QUESTION 4
ANALYSIS OF THE STUDY MODEL

Hypothesis 4.1

The amount of variance explained by the study models is statistically significant.

There were five independent variables per model. The two models tested in this study were the same overall, but with different specific behavioral intents and behaviors. The first model presented the behavioral intent and behavior related to obtaining a prostate exam. There were two different behavioral intents measured with this model. Each behavioral intent had a different level of effort.

Only a limited number of the respondents responded to the section attitude toward the product HytrinR. This was appropriate because only those respondents who had heard of HytrinR to treat BPH were asked to respond. This left a large group of nonrespondents to this section. The researcher therefore decided to impute the score of “4”
which corresponded to “neither disagree nor agree” with the statement or question for all those nonrespondents. If this was not done, there would not have been enough respondents to run the regression analysis. Only 89 respondents answered this section of the questionnaire completely. This small number would have violated the assumption of regression of approximately 30 respondents needed per independent variable in the model. Also, each behavior in this section was dichotomous and coded 0 for not exhibiting the behavior and 1 if the behavior was exhibited.

For the first model, presented in Table 34 and Figure 6, respondents were asked if they intended to ask their doctor to give them a prostate exam at their next scheduled appointment (behavioral intent #1). For the second model, presented in Table 35 and Figure 7, respondents were asked if they intended to make a special appointment to see their doctor to receive a prostate exam (behavioral intent #2). It is clear that behavioral intent #2 required a stronger effort than behavioral intent #1. Finally, the third model, presented in Table 36 and Figure 8, was related to obtaining a prescription for Hytrin®. The three attitude components...
are the same for both models, but the subjective norms and perceived behavioral control measures are different between model 3 and the other two in order to correspond with the respective behavioral intent and behavior. Therefore there are seven independent variables total, but only five per model.

The analysis was conducted using multiple regression analysis for each model with the behavioral intent as the dependent variable. Then a correlational analysis and logistical regression were conducted between the behavioral intent and the actual behavior. A predicted score for the behavioral intent, based on the five independent variables from each regression model, also was included in this correlational analysis. Two-way interactions between five independent variables in the models were not significant and therefore were not included in the model. The results are presented in Tables 34, 35, and 36 and Figures 6, 7, and 8.
<table>
<thead>
<tr>
<th>Variable</th>
<th>Beta Coeff.</th>
<th>Standardized Coeff.</th>
<th>T-ratio</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$A_o$</td>
<td>-0.01</td>
<td>-0.04</td>
<td>-0.74</td>
<td>0.47</td>
</tr>
<tr>
<td>$A_d$</td>
<td>0.01</td>
<td>0.04</td>
<td>0.73</td>
<td>0.46</td>
</tr>
<tr>
<td>$A_a$</td>
<td>-0.03</td>
<td>-0.05</td>
<td>-0.79</td>
<td>0.43</td>
</tr>
<tr>
<td>$SN_j$</td>
<td>0.01</td>
<td>0.26</td>
<td>4.13</td>
<td>0.0001</td>
</tr>
<tr>
<td>PBC</td>
<td>0.15</td>
<td>0.34</td>
<td>5.38</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Constant = 0.38

$n = 248$, $DF = 5$, Adjusted $R$ Square = 0.25, $F$ Ratio = 17.61, and $p$-value = .0001

$A_o = \text{attitude toward the product Hytrin}^R$

$A_d = \text{attitude toward DTCA}$

$A_a = \text{attitude toward asking the physician for a prescription for a specific drug product}$

$SN_j = \text{subjective norms of the individual regarding obtaining a prostate exam}$

$PBC = \text{perceived behavioral control in obtaining a prostate exam}$

(Behavioral intent #1 asked the respondent if they intended to ask for a prostate exam at their next scheduled doctor’s appointment)

**Table 34: Multiple Regression Analysis Results Of Behavioral Intent #1 (Asking for a Prostate Exam)**
$A_o$ = attitude toward the product  
$A_d$ = attitude toward DTCA  
$A_a$ = attitude toward asking the physician for a prescription for a specific drug product  
$SN_j$ = subjective norms of the individual regarding obtaining a prostate exam  
$PBC$ = perceived behavioral control in obtaining a prostate exam.  
$BI$ = behavioral intention to ask the doctor for a prostate exam at the next scheduled appointment  
$B$ = actual behavior of obtaining a prostate exam

* = Standardized beta coefficients  
** = Point biserial correlation (p-value = 0.001)  
*** = Point biserial correlation using the predicted BI derived from the model (p-value = 0.0001)  
**** = odds ratio from logistic regression (p-value = 0.0013)

Figure 6: Study Model with Standardized Beta Coefficients for Behavioral Intent #1 (Prostate Exam)
<table>
<thead>
<tr>
<th>Variable</th>
<th>Beta Coeff.</th>
<th>Standardized Coeff.</th>
<th>T-ratio</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$A_o$</td>
<td>-0.005</td>
<td>-0.02</td>
<td>-0.33</td>
<td>0.74</td>
</tr>
<tr>
<td>$A_d$</td>
<td>-0.0009</td>
<td>-0.006</td>
<td>-0.09</td>
<td>0.93</td>
</tr>
<tr>
<td>$A_a$</td>
<td>0.06</td>
<td>0.10</td>
<td>1.60</td>
<td>0.11</td>
</tr>
<tr>
<td>$SN_j$</td>
<td>0.01</td>
<td>0.24</td>
<td>3.46</td>
<td>0.0006</td>
</tr>
<tr>
<td>PBC</td>
<td>0.06</td>
<td>0.13</td>
<td>1.89</td>
<td>0.06</td>
</tr>
</tbody>
</table>

Constant = 0.96

$n = 248, \; DF = 5, \; Adjusted \; R \; Square = 0.09, \; F \; Ratio = 6.09, \; and \; p-value = .0001$

$A_o = \text{attitude toward the product Hytrin}^R$
$A_d = \text{attitude toward DTCA}$
$A_a = \text{attitude toward asking the physician for a prescription for a specific drug product}$
$SN_j = \text{subjective norms of the individual regarding obtaining a prostate exam}$
$PBC = \text{perceived behavioral control in obtaining a prostate exam}$

(Behavioral intent #2 asked the respondent if they intended to make a special appointment with their doctor to ask him/her for a prostate exam)

**Table 35: Multiple Regression Analysis Results Of Behavioral Intent #2 {Asking for a Prostate Exam}**
\[ A_o = \text{attitude toward the product} \\
A_d = \text{attitude toward DTCA} \\
A_a = \text{attitude toward asking the physician for a prescription for a specific drug product} \\
SN_j = \text{subjective norms of the individual regarding obtaining a prostate exam} \\
PBC = \text{perceived behavioral control in obtaining a prostate exam.} \\
BI = \text{behavioral intention to make a special appointment to ask the doctor for a prostate exam} \\
B = \text{actual behavior of obtaining a prostate exam} \\
\]

* = Standardized beta coefficients
** = Point biserial correlation (p-value = 0.001)
*** = Point biserial correlation using the predicted BI derived from the model (p-value = 0.0001)
**** = odds ratio from logistic regression (p-value = 0.0005)

**Figure 7** Study Model with Standardized Beta Coefficients for Behavioral Intent #2 (Prostate Exam)
<table>
<thead>
<tr>
<th>Variable</th>
<th>Beta Coeff.</th>
<th>Standardized Coeff.</th>
<th>T-ratio</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>$A_o$</td>
<td>0.01</td>
<td>0.06</td>
<td>0.96</td>
<td>0.34</td>
</tr>
<tr>
<td>$A_d$</td>
<td>0.002</td>
<td>0.02</td>
<td>0.32</td>
<td>0.75</td>
</tr>
<tr>
<td>$A_a$</td>
<td>0.03</td>
<td>0.07</td>
<td>1.07</td>
<td>0.28</td>
</tr>
<tr>
<td>$SN_i$</td>
<td>0.01</td>
<td>0.26</td>
<td>4.22</td>
<td>0.0001</td>
</tr>
<tr>
<td>$PBC_i$</td>
<td>0.08</td>
<td>0.07</td>
<td>1.18</td>
<td>0.24</td>
</tr>
</tbody>
</table>

Constant = 1.33

$n = 248$, DF = 5, Adjusted R Square = 0.08, F Ratio = 5.01, and p-value = .0002

$A_o$ = attitude toward the product Hytrin$^R$
$A_d$ = attitude toward DTCA
$A_a$ = attitude toward asking the physician for a prescription for a specific drug product
$SN_i$ = subjective norm of the individual regarding asking for a prescription for Hytrin$^R$ if the prostate was enlarged
$PBC_i$ = perceived behavioral control in obtaining a prescription for Hytrin$^R$ if the prostate was enlarged

(Behavioral intent #3 asked the respondent if they intended to ask for a prescription for Hytrin$^R$ if a prostate exam showed their prostate was enlarged and treatment was needed)

Table 36: Multiple Regression Analysis Results Of Behavioral Intent #3 (Asking for Rx for Hytrin)
$A_0 = \text{attitude toward the product}$

$A_d = \text{attitude toward DTCA}$

$A_s = \text{attitude toward asking the physician for a prescription for a specific drug product}$

$SN_i = \text{subjective norm of the individual regarding asking for a prescription for Hytrin}^R$ \text{if the prostate was enlarged}$

$PBC_i = \text{perceived behavioral control in obtaining a prescription for Hytrin}^R$ \text{if the prostate was enlarged}$

$BI = \text{behavioral intention to ask the doctor for a prescription for Hytrin}^R$ \text{if the prostate was enlarged}$

$B = \text{actual behavior of obtaining a prescription for Hytrin}^R$ \text{if the prostate was enlarged}$

* = Standardized beta coefficients

** = Point biserial correlation (p-value = 0.24)

*** = Point biserial correlation using the predicted BI derived from the model (p-value = 0.47)

**** = odds ratio (p-value = 0.24)

\textbf{Figure 8: Study Model with Standardized Beta Coefficients for Behavioral Intent #3 (Rx for Hytrin}$^R$)
For all three models, a statistically significant amount of variance was explained based on the adjusted R square. Therefore, Hypothesis 4.1 was supported. The amount of variance explained by the model was greatest for behavioral intent #1 (asking the doctor for a prostate exam at the patient’s next scheduled appointment) where the adjusted R square was 0.25. For behavioral intent #2 (making a special appointment to visit the doctor for a prostate exam) and behavioral intent #3 (asking the physician for a prescription for Hytrin<sup>R</sup> if a prostate exam indicated the need for treatment) the adjusted R square dropped to, 0.08 and 0.09 respectively. These results, although statistically significant, still show that other variables not measured by the researcher may further contribute to the overall variance explained.

Correlational analysis between behavioral intent and actual behavior are correlated regarding obtaining a prostate exam 0.22 and 0.23 with a p-value of 0.001 for both. But for the correlation regarding the behavior of obtaining a prescription for Hytrin<sup>R</sup> was extremely low
(0.08) and not statistically significant (p-value of 0.24). This provides evidence that measuring behavioral intent may not be a good surrogate endpoint for the actual behavior.

Logistic regression analysis for the behavior of obtaining a prostate exam was statistically significant for behavioral intent #1, Figure 6 \{-2 \text{ Log LR} = 10.40, \text{ df} = 1, p\text{ value} = .0013, \text{ odds ratio of} 1.25, \text{ and} 95\% \text{ confidence interval of} 1.43 \text{ to} 1.08\} \text{ and for behavioral intent} #2, Figure 7 \{-2 \text{ Log LR} = 11.95, \text{ df} = 1, p\text{ value} = .0005, \text{ odds ratio of} 1.26, \text{ and} 95\% \text{ confidence interval of} 1.44 \text{ to} 1.10\}. The logistic regression analysis for the behavior of obtaining a prescription for Hytrin\textsuperscript{R} was not statistically significant for behavioral intent #3, Figure 8 \{Residual Chi-square = 1.40, \text{ df} = 1, p\text{ value} = 0.24, \text{ odds ratio of} 1.22 \text{ and} 95\% \text{ confidence interval of} 1.69 \text{ to} 0.88\}. 
RESEARCH QUESTION 5
RETENTION OF RISK INFORMATION

Hypothesis 5.1

There is a difference in the retention of risk information among the three treatment groups (control group, disease specific institutional advertisement group, and the product specific advertisement group).

Respondents were asked 10 true/false statements about side effect and risk information regarding the product Hytrin®. True/false statements were developed from the actual text of the advertisement and from the brief summary on the back of the ad. Also, respondents were given the choice to answer “don’t know” for each question. Differences among the study groups were determined using Chi-square analysis. The results of this analysis are presented in Table 37.
EXPERIMENTAL GROUP

<table>
<thead>
<tr>
<th>Control (n=96-97)</th>
<th>Institutional Ad (n=75-76)</th>
<th>Product Specific Ad (n=81-82)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Question 1</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>5.2%</td>
<td>9.2%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>2.1%</td>
<td>2.6%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>92.7%</td>
<td>88.2%</td>
</tr>
<tr>
<td>Column Total</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>Question 2</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>6.2%</td>
<td>9.2%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>2.1%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>91.7%</td>
<td>89.5%</td>
</tr>
<tr>
<td>Column Total</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>Question 3</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>6.8%</td>
<td>11.8%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>4.2%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>89.5%</td>
<td>86.9%</td>
</tr>
<tr>
<td>Column Total</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>Question 4</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>3.1%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>2.1%</td>
<td>7.9%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>94.8%</td>
<td>92.1%</td>
</tr>
<tr>
<td>Column Total</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>Question 5</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>4.2%</td>
<td>6.7%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>2.1%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>93.7%</td>
<td>92.0%</td>
</tr>
<tr>
<td>Column Total</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

\[n = 256, \text{Chi-square} = 4.67, \text{DF} = 4, \text{and p-value} = 0.32\]

\[n = 256, \text{Chi-square} = 5.61, \text{DF} = 4, \text{and p-value} = 0.23\]

\[n = 256, \text{Chi-square} = 5.95, \text{DF} = 4, \text{and p-value} = 0.20\]

\[n = 256, \text{Chi-square} = 6.14, \text{DF} = 4, \text{and p-value} = 0.19\]

\[n = 252, \text{Chi-square} = 1.71, \text{DF} = 4, \text{and p-value} = 0.79\]

to be continued...

**Table 37: Risk Information Responses By Experimental Group**

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**Table 37: Continued**

<table>
<thead>
<tr>
<th>Question</th>
<th>Control (n=96-97)</th>
<th>Institutional Ad (n=75-76)</th>
<th>Product Specific Ad (n=81-83)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Correct</strong></td>
<td>4.2%</td>
<td>2.6%</td>
<td>3.6%</td>
</tr>
<tr>
<td><strong>Incorrect</strong></td>
<td>4.2%</td>
<td>6.6%</td>
<td>7.2%</td>
</tr>
<tr>
<td><strong>Don’t Know</strong></td>
<td>91.6%</td>
<td>90.8%</td>
<td>89.2%</td>
</tr>
<tr>
<td><strong>Column Total</strong></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

n = 255, Chi-square = 1.17, DF = 4, and p-value = 0.89

<table>
<thead>
<tr>
<th>Question</th>
<th>Control (n=96-97)</th>
<th>Institutional Ad (n=75-76)</th>
<th>Product Specific Ad (n=81-83)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Correct</strong></td>
<td>3.1%</td>
<td>3.9%</td>
<td>2.4%</td>
</tr>
<tr>
<td><strong>Incorrect</strong></td>
<td>2.1%</td>
<td>3.9%</td>
<td>4.8%</td>
</tr>
<tr>
<td><strong>Don’t Know</strong></td>
<td>94.8%</td>
<td>92.2%</td>
<td>92.8%</td>
</tr>
<tr>
<td><strong>Column Total</strong></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

n = 255, Chi-square = 1.33, DF = 4, and p-value = 0.86

<table>
<thead>
<tr>
<th>Question</th>
<th>Control (n=96-97)</th>
<th>Institutional Ad (n=75-76)</th>
<th>Product Specific Ad (n=81-83)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Correct</strong></td>
<td>4.2%</td>
<td>10.5%</td>
<td>13.3%</td>
</tr>
<tr>
<td><strong>Incorrect</strong></td>
<td>3.1%</td>
<td>0.0%</td>
<td>1.2%</td>
</tr>
<tr>
<td><strong>Don’t Know</strong></td>
<td>92.7%</td>
<td>89.5%</td>
<td>85.5%</td>
</tr>
<tr>
<td><strong>Column Total</strong></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

n = 255, Chi-square = 7.35, DF = 4, and p-value = 0.12

<table>
<thead>
<tr>
<th>Question</th>
<th>Control (n=96-97)</th>
<th>Institutional Ad (n=75-76)</th>
<th>Product Specific Ad (n=81-83)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Correct</strong></td>
<td>3.1%</td>
<td>1.3%</td>
<td>3.7%</td>
</tr>
<tr>
<td><strong>Incorrect</strong></td>
<td>4.2%</td>
<td>7.9%</td>
<td>8.5%</td>
</tr>
<tr>
<td><strong>Don’t Know</strong></td>
<td>92.7%</td>
<td>90.8%</td>
<td>87.8%</td>
</tr>
<tr>
<td><strong>Column Total</strong></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

n = 254, Chi-square = 2.48, DF = 4, and p-value = 0.65

<table>
<thead>
<tr>
<th>Question</th>
<th>Control (n=96-97)</th>
<th>Institutional Ad (n=75-76)</th>
<th>Product Specific Ad (n=81-83)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Correct</strong></td>
<td>3.1%</td>
<td>5.3%</td>
<td>6.1%</td>
</tr>
<tr>
<td><strong>Incorrect</strong></td>
<td>6.3%</td>
<td>0.0%</td>
<td>4.9%</td>
</tr>
<tr>
<td><strong>Don’t Know</strong></td>
<td>90.6%</td>
<td>94.7%</td>
<td>89.0%</td>
</tr>
<tr>
<td><strong>Column Total</strong></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

n = 254, Chi-square = 5.52, DF = 4, and p-value = 0.24
Before interpreting the above table, it’s important to note that for every question and for all three groups more than 80% of the respondents within each group indicated they did not know the answer to the question. Therefore only a small percentage even attempted to answer the question. Also, the number in each group who responded to a particular question did change very slightly between questions. This is the reason the n-values for each group are given as a range. At first glance, it appears that for many of the questions the group who received the ad for Hytrin® (Product Specific Ad Group) had a slightly higher percentage of correct answers. This illustrates that the product specific ad group experienced some risk information retention by the respondents. However, Chi-square analysis using all the respondents (including those who reported “don’t know”) showed a different result.

There was no statistically significance difference among the three groups regarding the correct answering of any of the ten risk information questions. The interventions had no effect on respondents’ recall of risk information as demonstrated by the lack of answering risk
information questions correctly. Therefore, Hypothesis 5.1
was not supported. Also, the data were analyzed by
collapsing the “don’t know” responses with those that
answered the question incorrectly. Again Chi-square
analysis showed no significant difference among the three
groups for any of the risk information questions (all Chi-
square p-values were greater than 0.05).

Finally, an overall composite score for all ten
questions was computed. The composite score was computed by
giving the respondent one point for each correct answer and
zero points for an incorrect or don’t know response. The
range of possible scores is from 0-10. One way analysis of
variance was used to determine differences in these
composite scores among the three groups. The results are
presented in Table 38.
<table>
<thead>
<tr>
<th>EXPERIMENTAL GROUP</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>96</td>
<td>0.43</td>
<td>0-7</td>
<td>0.14</td>
</tr>
<tr>
<td>Institutional Ad</td>
<td>75</td>
<td>0.53</td>
<td>0-6</td>
<td>0.18</td>
</tr>
<tr>
<td>Product Specific Ad</td>
<td>81</td>
<td>0.68</td>
<td>0-6</td>
<td>0.17</td>
</tr>
</tbody>
</table>

n = 252, F Ratio = 0.64, DF = 251, and F Probability = 0.53

Table 38: Composite Scores for Risk Information

Based on this analysis, hypothesis 5.1 again is not supported. There was no significant difference among the three groups in their composite scores regarding risk information retention. There were, however, some other interesting finding regarding risk information retention.

A second analysis was conducted on the same ten questions using two different factors. The percentage of questions answered correctly was analyzed based on whether the respondent had used Hytrin™ in the past and whether or not they had seen an ad for Hytrin™ in the past. In this study, actual ads for Hytrin™ were used. These ads had been used in the past as well as many other different types of ads for Hytrin™. This accounts for some individuals in the
control and disease specific ad groups, as well as the product specific ad group, having responded that they had seen an ad for Hytrin® in the past.

Respondents were asked if they had seen an ad for Hytrin® in the last 3 months. Based on this information, respondents were categorized into one of four groups: 1) No, they had not taken Hytrin® in the past and No, they had not seen an ad for Hytrin® in the past, 2) No, they had not taken Hytrin® in the past and Yes, they had seen an ad for Hytrin® in the past, 3) Yes, they had taken Hytrin® in the past and No, they had not seen an ad for Hytrin® in the past, and 4) Yes, they had taken Hytrin® in the past and Yes, they had seen an ad for Hytrin® in the past. Chi-square analysis was conducted to determine the difference among the four groups regarding the correct answering of the risk questions. The results are presented in Table 39.
<table>
<thead>
<tr>
<th></th>
<th>Not Taken Hytrin and Not Seen Ad (n=196-197)</th>
<th>Not Taken Hytrin and Seen an Ad (n=27-29)</th>
<th>Taken Hytrin and Not Seen Ad (n=6)</th>
<th>Taken Hytrin and Seen an Ad (n=16-17)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question 1</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>2.5%</td>
<td>25.0%</td>
<td>50.0%</td>
<td>52.9%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>1.0%</td>
<td>3.6%</td>
<td>16.7%</td>
<td>11.8%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>96.5%</td>
<td>71.4%</td>
<td>33.3%</td>
<td>35.3%</td>
</tr>
<tr>
<td>Column Total</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>n = 248, Chi-square = 82.95, DF = 6, and p-value = 0.00001</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Question 2</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>1.5%</td>
<td>14.3%</td>
<td>50.0%</td>
<td>52.9%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>1.5%</td>
<td>14.3%</td>
<td>16.7%</td>
<td>5.9%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>97.0%</td>
<td>71.4%</td>
<td>33.3%</td>
<td>41.2%</td>
</tr>
<tr>
<td>Column Total</td>
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<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>n = 248, Chi-square = 93.90, DF = 6, and p-value = 0.00001</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Question 3</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>3.1%</td>
<td>37.9%</td>
<td>50.0%</td>
<td>47.1%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>0.5%</td>
<td>0.0%</td>
<td>16.7%</td>
<td>23.5%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>96.4%</td>
<td>62.1%</td>
<td>33.3%</td>
<td>29.4%</td>
</tr>
<tr>
<td>Column Total</td>
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<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>n = 248, Chi-square = 109.84, DF = 6, and p-value = 0.00001</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Question 4</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>0.5%</td>
<td>3.4%</td>
<td>33.3%</td>
<td>5.9%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>2.6%</td>
<td>17.2%</td>
<td>33.3%</td>
<td>17.6%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>96.9%</td>
<td>79.4%</td>
<td>33.4%</td>
<td>76.5%</td>
</tr>
<tr>
<td>Column Total</td>
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<td>100.0%</td>
<td>100.0%</td>
</tr>
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<td><strong>n = 248, Chi-square = 57.80, DF = 6, and p-value = 0.00001</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Question 5</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>3.1%</td>
<td>19.2%</td>
<td>16.7%</td>
<td>25.0%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>0.0%</td>
<td>0.0%</td>
<td>16.7%</td>
<td>18.8%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>96.9%</td>
<td>80.8%</td>
<td>66.6%</td>
<td>56.2%</td>
</tr>
<tr>
<td>Column Total</td>
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<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td><strong>n = 244, Chi-square = 63.26, DF = 6, and p-value = 0.00001</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

to be continued...

Table 39: Risk Information Responses Based on Past Use of Hytrin and Seeing an Advertisement for Hytrin
### Table 39: Continued

<table>
<thead>
<tr>
<th></th>
<th>Not Taken Hytrim and Not Seen Ad (n=196-197)</th>
<th>Not Taken Hytrim and Seen an Ad (n=27-29)</th>
<th>Taken Hytrim and Not Seen Ad (n=6)</th>
<th>Taken Hytrim and Seen an Ad (n=16-17)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Question 6</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>0.5%</td>
<td>10.7%</td>
<td>16.7%</td>
<td>23.5%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>2.6%</td>
<td>10.7%</td>
<td>50.0%</td>
<td>23.5%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>96.9%</td>
<td>78.6%</td>
<td>33.3%</td>
<td>53.0%</td>
</tr>
<tr>
<td><strong>Column Total</strong></td>
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<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>n</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Question 7</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>1.0%</td>
<td>7.1%</td>
<td>16.7%</td>
<td>17.6%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>1.5%</td>
<td>7.1%</td>
<td>33.3%</td>
<td>11.8%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>97.5%</td>
<td>85.8%</td>
<td>50.0%</td>
<td>70.6%</td>
</tr>
<tr>
<td><strong>Column Total</strong></td>
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<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>n</td>
<td>247, Chi-square = 42.15, DF = 6, and p-value = 0.00001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Question 8</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>3.1%</td>
<td>28.6%</td>
<td>50.0%</td>
<td>35.3%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>0.5%</td>
<td>0.0%</td>
<td>16.7%</td>
<td>11.8%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>96.4%</td>
<td>71.4%</td>
<td>33.3%</td>
<td>52.9%</td>
</tr>
<tr>
<td><strong>Column Total</strong></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>n</td>
<td>247, Chi-square = 70.26, DF = 6, and p-value = 0.00001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Question 9</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>0.5%</td>
<td>3.7%</td>
<td>33.3%</td>
<td>17.6%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>2.6%</td>
<td>14.8%</td>
<td>33.3%</td>
<td>35.3%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>96.9%</td>
<td>81.5%</td>
<td>33.4%</td>
<td>47.1%</td>
</tr>
<tr>
<td><strong>Column Total</strong></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>n</td>
<td>246, Chi-square = 77.10, DF = 6, and p-value = 0.00001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Question 10</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Correct</td>
<td>2.0%</td>
<td>14.8%</td>
<td>16.7%</td>
<td>17.6%</td>
</tr>
<tr>
<td>Incorrect</td>
<td>1.5%</td>
<td>3.7%</td>
<td>16.7%</td>
<td>29.4%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>96.4%</td>
<td>81.5%</td>
<td>66.7%</td>
<td>52.9%</td>
</tr>
<tr>
<td><strong>Column Total</strong></td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
<td>100.0%</td>
</tr>
<tr>
<td>n</td>
<td>246, Chi-square = 52.41, DF = 6, and p-value = 0.00001</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
As in the previous analysis on risk information, the n-values are given as a range since a slightly different amount of respondents answered some questions. There was a statistically significance difference among the four groups regarding the correct answering of all ten risk information questions. The data analysis shows a larger percentage of respondents answered the risk information questions correctly from the last two groups, those that had taken Hytrin\textsuperscript{R} is the past (columns 3 and 4), as compared to those from the first two groups, those who had not taken Hytrin\textsuperscript{R} (columns 1 and 2). This shows that experience regarding the use of the product does have an affect on risk information retention. The group that had experience with using the product may have received the risk information from patient-pharmacist counseling, from the physician, or from written patient product information distributed by the pharmacist with the prescription. In contrast, we also noticed that the groups that had taken Hytrin\textsuperscript{R} in the past answered more of the risk questions incorrectly. This may be interpreted as experience with the product provides a false sense of knowledge about some aspects of risk information.
When comparing those respondents who had not seen an ad with those who had seen an ad only for those who had not taken Hytrin® (columns 1 and 2), a higher percentage of respondents that had seen an ad answered the questions correctly. This shows that having seen an ad for the product Hytrin® resulted in a higher percentage of the respondents answering the question correctly. The difference in the results of the two analyses (Tables 37 and 39) could be due to a couple of other variables not under the control of the researcher.

First, the medium for this study was direct mail. Other individuals who responded to seeing an ad for Hytrin® but did not receive our ad may have seen Hytrin® ads on television or in newspapers or magazines. Therefore, the type of medium used to deliver risk information may have some affect. Second, our ads were black and white and many magazine ads are in color. This may also explain some of the difference. Finally, our study participants only received three ads through the mail. This represents only three possible exposures. Other participants, who indicated having seen an ad for Hytrin®, may have had multiple
exposures from other different forms of media. This again
could explain the difference in results for the two analyses
of risk information retention. The results show, however,
that consumers are retaining some risk information from
direct-to-consumer advertisements.

A composite score also was calculated for each of the
four groups using the same method as for the three
experimental groups. The range of possible scores is from
0-10. One way analysis of variance was used to determine
differences in these composite scores among the four groups.
The results are presented in Table 40.

<table>
<thead>
<tr>
<th>GROUP</th>
<th>n</th>
<th>Mean</th>
<th>Range</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Not Taken Hytrin and Not Seen an Ad</td>
<td>196</td>
<td>0.18</td>
<td>0-5</td>
<td>0.06</td>
</tr>
<tr>
<td>2) Not Taken Hytrin and Seen an Ad</td>
<td>26</td>
<td>1.42</td>
<td>0-6</td>
<td>0.40</td>
</tr>
<tr>
<td>3) Taken Hytrin and Not Seen an Ad</td>
<td>6</td>
<td>3.33</td>
<td>0-7</td>
<td>1.26</td>
</tr>
<tr>
<td>4) Taken Hytrin and Seen an Ad</td>
<td>16</td>
<td>2.75</td>
<td>0-7</td>
<td>0.54</td>
</tr>
</tbody>
</table>

n = 244, F Ratio = 36.78, DF = 243, and F Probability = 0.00001

Table 40: Composite Scores for Risk Information Based
on Past Use of Hytrin and Seeing an Advertisement for Hytrin
Based on this analysis, there was a significant difference among the four groups in their composite scores regarding risk information retention (F Ratio = 36.78 and F Probability = 0.00001). Post hoc analysis using the Least Significant Difference (LSD) Test and Scheffe’s Test showed a difference in composite scores between the group that had not taken Hytrin and not seen an ad (group 1) and each of the other three groups (groups 2, 3, and 4). Post hoc analysis also showed a difference between the group had not taken Hytrin and seen an ad (group 2) and the two groups that had taken Hytrin (groups 3 and 4). These results show that having seen an ad in the past does increase risk information retention, but past experience in taking the product provides an even greater degree of retention of risk information.
CHAPTER 5

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

This chapter will provide a detailed discussion of each research question including recommendations and future areas for research. The chapter will then conclude with a section entitled Implications for Theory of Planned Behavior.

Research Question 1

What is the effect of a product specific advertisement, or disease specific institutional advertisement on a consumer's attitude toward DTCA, attitude toward the product, and attitude toward asking the physician for a prescription for a specific drug product?
This question measured the differences in the respondent’s attitudes among the three treatment groups (control group, disease specific institutional advertisement group, and the product specific advertisement group). In the evolution of the Fishbein Model to its current form (Ajzen’s Theory of Planned Behavior), the attitude component always has been a single construct within the model. When this study was first conceptualized, the researcher believed that the attitude component for these given health behaviors was not a single construct based on previous research by Morris et al. (1986a and 1986b). The researcher believed that there were three separate and distinct attitude constructs and each one may have a different effect on the final behaviors. These constructs were: 1) attitude toward DTCA, 2) attitude toward the product Hytrin®, and 3) attitude toward asking the physician for a prescription for a specific product.

When the three attitude constructs were analyzed by one way analysis of variance, no significant differences were found among the three groups on each attitude. Essentially, the intervention of sending 3 sets of advertisements through
the mail at one week intervals had no effect on patient attitudes (See Tables 9,11, and 13). This lack of effect could be interpreted in several ways.

First and the most simplistic interpretation is that DTCA itself is not effective in changing patient's attitudes. This conclusion probably is unfounded since research on real prescription products in a field-type setting is limited. Proxy measures, such as increases in market share or phone calls to a toll-free number displayed in the ad, may lend some evidence to influence of patient attitudes, but this is just speculation. Until further methodologically sound research is conducted on real products in a field setting, the extent of the ability of DTCA to affect attitudes is still somewhat of a mystery. More research needs to be conducted in this area.

Another reason for lack of affect on attitudes could have been the advertisements themselves. The disease specific advertisement was comprised of actual pieces of advertisements from Merck & Co. and Abbott Laboratories. The product specific advertisement for Hytrin® was an actual DTCA used by Abbott Laboratories. Real ads were used in the
study to help strengthen the external validity. Most of the past research on DTCA has been conducted with fictitious products.

The advertisements of Merck & Co. and Abbott Laboratories were probably designed by an advertising agency and were most likely not tested before use. This could lead to the possible conclusion that the ads themselves may have been ineffective in affecting attitudes. This could be due to poor persuasiveness of the copy message, unappealing graphics, or the information within the ads was too technical for consumers to process, but still more consumer friendly than other DTCA. Another point to consider is that strong attitudes may have already been formed regarding DTCA and BPH. This may also account for the lack of effect on attitudes of the interventions.

Finally, the medium used to present the advertisements (i.e. direct mail) may have contributed to the lack of effect. This medium was chosen due to cost considerations of the study. The researcher does not even know for sure if the ads were actually read. Consumers could have viewed the advertisements as nothing more than junk-mail and thrown
them away. The results would suggest that the ads were read by some of the study sample because recall of seeing an ad for Hytrin\textsuperscript{R} was significantly higher for the product specific advertisement group than the other two groups (See Tables 30 and 31.) These results show the ads did get read, but still did not have an effect on attitudes. Also, three exposures to the advertisement may not have been enough to affect attitudes.

The researcher believes that lack of persuasion of the ad copy (which was not under the control of the researcher) and the single-modality (direct mail) in which the ads were delivered most likely contributed to the lack of effect on patient attitudes. Better ad copy using multiple modalities (newspaper, direct mail, radio, television, magazines, etc.) with several exposures could produce some effect on patient attitudes. Therefore future research incorporating these suggestions needs to be conducted.
Research Question 2

What is the effect of a product specific advertisement, or disease specific institutional advertisement on a consumer's subjective norms, perceived behavioral control, behavioral intent, and actual behavior?

This question measured the differences in the respondent’s subjective norms, perceived behavioral control, behavioral intent, and actual behavior among the three treatment groups (control group, disease specific institutional advertisement group, and the product specific advertisement group).

The affect on the patient’s subjective norms and perceived behavioral control were not found to be statistically significant among the three groups (Tables 15-20). One explanation for this is that the advertisements used in this study contained no information or persuasive arguments to try to affect these constructs. The advertisements used in the study were designed with
persuasive statements to try to affect patient attitudes. Evidently, subjective norms and perceived behavioral control were possibly not viewed as important in influencing and affecting final behaviors by the companies' that produced these ads. Some interesting findings in the descriptive analysis of this data lends to the credibility of the importance of subjective norms and perceived behavioral control.

The results of subjective norms, combining all of the respondents together, showed that 94% of the respondents indicated that they want to do what their doctor thinks they should do and 74% of the respondents want to do what their family thinks they should do. This shows the high level of persuasive power that these two groups have over this cohort of consumers. The results of the perceived behavioral control in obtaining a prostate exam showed that 89% responded they had the time to discuss prostate problems with their physician, 69% were motivated to do so, and 78% felt they could convince their physician to give them a prostate exam. For the behavior of asking for a prescription for Hytrin®, 89% still had the time, but only
23% were motivated and only 19% felt they had the ability to convince the physician to write a prescription for Hytrin®.

These results suggest that DTCA should contain information regarding the subjective norms using the referent groups of physician and family. For example: “Your family is concerned about your health and thinks you should discuss your prostate problems and treatments such as Hytrin® with your doctor.” Statements like this would incorporate subjective norms important to the consumer and should increase their perceived feeling of ability and motivation to talk to their doctor about the product. The affect of subjective norms and perceived behavioral on health behaviors will be discussed in further detail under Research Question 4.

The affects on behavioral intent and actual behavior for each of the two behaviors in question (obtaining a prostate exam and obtaining a prescription for Hytrin®) were not statistically significant among the three groups. These results showed that the ads had no effect on the intent to or behavior of obtaining a prostate exam or obtaining a prescription for Hytrin®. This is consistent with the
findings that none of the five independent variables in the model were significant among the three groups.

Regarding the actual behavior of obtaining a prostate exam, physician visits were analyzed among the groups in case a prostate exam was not given but a PSA test was provided in its place. Again, no significant difference was observed among the three groups. Interpretation of the full model will be discussed in detail in Research Question 4.

A prostate exam can be an unpleasant procedure. Therefore an intervention to persuade an individual to seek-out an undesirable procedure and convince them it is best for them must be a strong one. Another way to possibly overcome this problem could be to bombard the consumer with several ads through several different types of media and increase the persuasiveness of the ads. Multiple exposures of more persuasive ads are probably the best chance to affect these types of health behaviors. From this study, however, it is evident that DTCA may not be an effective tool in convincing patients to seek-out unpleasant procedures.
Behavioral intent in obtaining a prostate exam was measured using two different questions. The first question asked the intent of obtaining a prostate exam at the next scheduled doctor's appointment. The mean for the control group was 4.72, institutional ad group 4.53, and product specific ad group 4.78 (Likert-type scale 1 = strongly disagree to 7 = strongly agree). The second question required more effort from the patient. This question asked the intent of making a special appointment to see a doctor and obtain a prostate exam. The mean for the control group on this question was 3.74, institutional ad group 3.52, and product specific ad group 3.71.

The institutional ad group received an ad touting the need and benefits from receiving a prostate exam exclusively. In both behavioral intent questions regarding obtaining a prostate exam, this group had the lowest score. Even though this difference is not statistically significant, the trend of scores is still interesting. This group had the lowest average behavioral intention of obtaining a prostate exam of the three. This may suggest that prostate problems are a very private matter to men.
Any advertisement specifically discussing only prostate problems (disease specific institutional ad) may lead to the formation of more negative behavioral intentions.

Secondly, the behavioral intent score for the second question that required more patient effort was lower than the first question across all three groups. This may indicate that under these conditions and circumstances that the more effort required by a patient to exhibit a given behavior as measured by intent, the lower the behavioral intent scores would be. This has vast implications in how researchers word behavioral intent questions regarding complex health behaviors. This also lends insight into the fact that health related behaviors that require several steps to perform may lead to low behavioral intent scores.

There was, however, some evidence that suggests the advertisements were effective in some respects. Respondents were asked if they had ever seen an ad for Hytrin® for use in treating an enlarged prostate. An enlarged prostate was specifically mentioned since the drug is also used for hypertension. A significantly larger proportion of respondents had seen an ad for Hytrin® in the product
specific ad group compared to the control and institutional ad groups (see Tables 30 and 31). This shows the ads did affect recall. However, the ability to recall seeing an ad for the product was the extent of effectiveness. Attitudes, subjective norms, perceived behavioral control, behavioral intent and actual behavior were not affected by the ads. Possibly more exposures to the ads, different choice of media, and/or more effective ads may have taken the level of processing by the consumer from simple recall to the next level, attitude formation and stronger behavioral intents (Ajzen and Fishbein, 1980 and Ajzen, 1991).

**Research Question 3**

Are there relationships or inter-relationships between attitude towards DTCA, attitude toward the product, attitude toward asking the physician for a prescription for a specific drug product, a consumer's subjective norms, and perceived behavioral control?
In the original model developed by Ajzen, all of the independent variables were believed to influence one another. This was represented by the bi-directional arrows between the independent variables in the model. Early work with the model showed correlations did exist between the independent variables, but more recent work indicates that this may not always be true (Ajzen, 1991).

The researcher tested the study model to determine if any relationships existed between pairs of the five independent variables in the study. Correlational analysis showed that none of the independent variables for either of the two models tested exhibited a relationship of any appreciable strength. (see Tables 32 and 33). However, two of the variables were slightly correlated, subjective norms in obtaining a prostate exam and the perceived behavioral control in obtaining a prostate exam (0.41) and subjective norm in obtaining a prescription for HytrinR and the attitude toward the product HytrinR (0.29).

The positive correlation between the subjective norm of obtaining a prostate exam and the perceived behavioral in obtaining a prostate exam goes back to Ajzen’s theory that
all the independent variables are inter-related. This theory is based on past research (Ajzen, 1991).

It is difficult for the researcher to interpret this correlation. Subjective norms are defined as a social factor. It is the level of consumer motivation to do what he thinks important referent groups think he should do. Perceived behavioral control, on the other hand, measures how much control the consumer has in a given situation regarding a specific behavior. If both of these variables are positively correlated, this means the higher the score for subjective norms the higher the score for perceived behavioral control. This is somewhat counter-intuitive. Interpreting this correlation means the stronger the motivation to do what referent groups thinks the consumer should is directly proportional to how much control the consumer thinks he has in a given behavioral situation.

Possible explanations are that a supportive family member or physician can give an individual a greater sense of perceived behavioral control or this finding may just be a idiosyncrasy of the study. The correlation was relatively weak. However, future research should be conducted to
determine the magnitude and extent of the possible relationship between subjective norms and perceived behavioral control especially in the use of the model to explain or predict health-related behaviors.

The second correlation between attitude toward the product Hytrin® and subjective norms in obtaining a prescription for the product Hytrin®, although weaker than the first (0.29), is somewhat easier to understand. Attitude is defined as the degree to which an individual has a favorable or unfavorable evaluation or appraisal of the behavior in question (Ajzen, 1991). Subjective norms are defined as the social pressure to perform or not perform a given behavior (Ajzen, 1991).

Subjective norms or social pressure may directly or indirectly affect the attitudes of a consumer toward a product or a given behavior. We know that attitudes are resilient. Long after an individual forgets why (the factors or reasons) he formed a positive or negative attitude toward a behavior or product, the attitude regarding a particular behavior remains. Attitudes are cognitive short-cuts for consumers. For example: a consumer
may have a negative attitude toward a prescription drug (e.g. an oral antibiotic in suspension form) based on past use. This may stem from an evaluation long ago when the consumer evaluated all the attributes of the drug (side effects experienced, adverse drug reactions, perceived efficacy, inconvenience of dosing, bad taste, etc.). The consumer may not remember all the attributes evaluated, but instead forms the negative attitude towards the drug.

Subjective norms may have the same effect on attitudes. High subjective norm scores suggests that the consumer is motivated to comply with beliefs of some important referent group. These beliefs may be incorporated into this cognitive short-cut of attitude formation. Using the same example above: Not only does the consumer have his own evaluation or experience with the product, but maybe a family member or the consumer’s physician feels the drug is not a good choice. This most likely also influences the consumer attitude towards the product. In the future, the consumer may not remember what the physician or family member said about the drug, but these social factors may have influenced attitude formation which is readily
accessible cognitively. Therefore, the relationship between subjective norms and attitudes is understandable. A future area for research may be determining a better method of separating-out the subjective norm component from the attitude component especially if the attitude has been formed a long time ago. In this situation, can the consumer really distinguish between the which of the two is contributing the most to behavioral intent or actual behavior?

For this study, however, the researcher believes that the correlations of the independent variables were not strong enough to conclude inter-relationships between the variables. Therefore, no single or bi-directional arrows were included between the independent variables. This analysis also indicated the lack of multicollinaerity of the independent variables. Also, interaction analysis of the independent variables also assisted in confirming the above conclusion.
Research Questions 4

Does the data set fit the proposed study model using multiple regression testing and correlational analysis?

In Research Question 4, explanatory power of the study model was tested. There were three separate models, but in essence each contained the same constructs. Three different models were used due to the different components of the behavior studied. In each model the same three attitude variables were incorporated. These were attitude toward DTCA, attitude toward the product Hytrin®, and attitude toward asking the physician for a prescription for a specific product. Subjective norms and perceived behavior control also were used in both models, but were different variables because the behavior of interest changed. Multiple regression analysis was used to assess the amount of variance the models explained.

The first model (Figure 6) included the dependent variable (Behavioral Intent #1) asking the physician for a
prostate exam at the next scheduled appointment. The adjusted R square = 0.25 and the p-value = 0.0001. This shows that the regression model explained 25% of the total variance in behavioral intent and was statistically significant. Of the five independent variables in the model, none of the attitude variables were significant. However, the subjective norm of the individual regarding obtaining a prostate exam and the perceived behavioral control in obtaining a prostate exam were significant.

Similar results were found for the second model (Figure 7). This model was identical to Figure 6, except the behavioral intent was changed to one that required more effort on the part of the patient. The behavioral intent (Behavioral Intent #2) in this model was, the patient would make a special appointment with his physician to obtain a prostate exam. This regression model also explained a significant proportion of the variance in behavioral intent (Adjusted R Square = 0.09. and p-value of 0.001), but actually explained less variance than the first. As with the first model, none of the attitudes contributed
significantly to the total variance explained, but the subjective norms did. Perceived behavioral control (p-value = 0.06) was just outside the a priori alpha value of 0.05.

Correlational analysis between behavioral intent, predicted behavioral intent (derived from the model) and actual behavior also was conducted. Logistic regression between behavioral intent and actual behavior was conducted as well. The results showed a significant correlation between the behavioral intent and the actual behavior and the predicted behavioral intent and the actual behavior for models one and two. The magnitude of the correlation, however, is relatively low. This shows that there is a relationship between the behavioral intent and the actual behavior, although for this study it is a small one. Logistic regression also showed that the behavioral intent for both models was a significant predictor of actual behavior.

The third model (Figure 8) in the study included the behavioral intent of asking the doctor for a prescription for Hytrin® if a prostate exam showed the prostate was
enlarged and needed treatment (Behavioral Intent #3). The subjective norm and perceived behavioral control were changed to reflect the change in the behavior of interest (see Table 36). The regression model explained a significant proportion of the variance in behavioral intent (adjusted R square = 0.03 and p-value = 0.0002). However, the proportion of variance explained by the model is quite low. Also, the only independent variable that significantly contributed to the variance of the model was the subjective norm of the individual regarding asking for prescription for Hytrin® if the prostate was enlarged.

Correlational analysis between behavioral intent or predicted behavioral intent (derived from the model) and actual behavior was conducted as well. Logistical regression between the behavioral intent scores and actual behavior also was conducted. The results showed that the correlation between the behavioral intent and the actual behavior and the predicted behavioral intent and the actual were not significant. This showed that for this particular behavior, there is no significant relationship between the behavioral intent and the actual behavioral. Logistical
regression showed that the behavioral intent was not a significant predictor of actual behavior for Behavioral Intent #3. This will be discussed further in the section on Implications for the Theory of Planned Behavior.

For the three models tested, even though a significant proportion of the variance was explained by each model, the total amount of variance explained was relatively small. This means that there were other variables not included by the researcher in the study that would help explain more of the variance. This was expected by the researcher because of the complex process and number of steps required of the consumer to exhibit the final behavior, obtaining a prostate exam and obtaining a prescription for Hytrin® if treatment was needed. The process of identifying a need for a prescription product and eventually having that prescription filled is a complex one. In summary, the patient must see the ad for the product, recognize the problem, self diagnose or seek proper diagnosis, make the time to have the appropriate medical testing or evaluation conducted, make the decision that treatment is warranted, convince the doctor to write a specific product or accept the doctor’s
recommendation, take the prescription to a pharmacy to be
dispensed, have the financial resources to pay for the
prescription, actually pick-up the finished prescription,
and then comply with the treatment regimen in order to
achieve the desired benefits from the therapy.

During this complex and lengthy series of events,
several things could derail the process. Some of these are
listed below:

1) the patient may not have the time or money to seek
diagnosis and treatment by a physician,

2) the patient or physician may misdiagnose the
problem,

3) the physician may not believe that the patient
should have input into prescription drug therapy,

4) the patient may feel that suggesting drug
therapy, no matter how positive their attitude
toward the product, is not a prerogative of the
patient in the patient-physician relationship,

5) the physician may chose a product different from
the one the patient suggests,
6) the patient may receive the prescription but never take it to be filled because of financial constraints, time constraints, or the feeling the problem is not that bad or is getting better and therapy is not needed at this time,

7) the pharmacy may be out of the product at that time,

8) the pharmacist may find a drug interaction with the prescribed drug and another medication the patient is taking,

9) formulary considerations may prevent the patient from having that particular product dispensed, and

10) the patient may drop off the prescription to be filled, but never return to pick-up.

Anyone of the above mentioned variables could alter the process leading to the final behavior. It also must be remembered that the physician has the final decision in prescribing, so the patient does not have final control over the behaviors of interest in this study.
The solution to this problem would be to try to develop a model that incorporates all of these missing variables. This could increase the proportion of variance explained. There are, however, problems with this mode of thinking. The first would be the ability to identify all the relevant variables needed to explain the behavior of interest. Past research and researcher intuition could be used, but these attempts would still most likely contain deficiencies.

Another problem would be the ease of use of the model. Models are designed to help researchers understand complex problems. A model with too many variables becomes too cumbersome to use and lacks practical application. The researcher must weigh the trade-off between the extra explanatory power of the model versus the number of variables that need to be added to achieve this. In some cases, such as, a simpler model with less explanatory power may be more applicable than a large, complex one with greater explanatory power. This is not to say improvements could not be made on the study model. However, ease of use and application are noteworthy considerations.
There are a few other things to consider from the results presented in these two models (see Figures 6 & 7 and Tables 34 and 35). As stated above, none of the attitudes measured contributed significantly to the total variance. This is a very important since many DTCA are designed to affect patient attitudes. The results of this study suggest that subjective norms and perceived behavioral control are the two components that DTCA should try to affect. These are the factors that seem to determine the effectiveness or success of the ad in influencing behavioral intentions.

These analyses showed that DTCA which contain appeals to affect subjective norms and perceived behavioral control may have a greater potential for affecting behavior than those focusing on affecting attitudes. Prescription drug ads for Hytrin® seem to have little affect on attitudes of the patient. Since DTCA must have the patient convince the physician to write for the product to be successful, appeals affecting the patient’s feeling of perceived behavioral control in that situation should be included. Also for older individuals, what other people think they should do (family and physician), is an important determinant and DTCA
should also include appeals to affect subjective norms. In summary, changing or affecting attitudes may not be a useful method for affecting health care-related behaviors. Health promotion material, such as DTCA, should focus on affecting subjective norms and perceived behavioral control.

Another consideration is the level of behavioral intent chosen may have an effect on the explanatory power of the model. For the model with the behavioral intent #1, the adjusted R square was 0.25, but for the model with behavioral intent #2 the adjusted R square was only 0.09. The same independent variables were used in both models as well as the same behavioral intent with only the level of effort changed.

For this study, the differences between behavioral intent #1 and #2 were the extra effort the patient had to make to exhibit the behavior of interest. These models (Figures 6 and 7) are not directly comparable because of the different dependent variables and the differences in their distributions. It can be stated, however, that under these circumstances and conditions, changing the level of effort in the behavioral intent may have contributed to the
decrease in the explanatory power of the model. The researcher feels this decrease may be due to the extra number of steps required by the patient to make a special appointment to see the doctor for a prostate exam.

From these findings, the following theoretical implications regarding the measurement of behavioral intent should be considered. In the future when behavioral intent is to be measured, the researcher should be extremely careful in the wording of the behavioral intent statement and the level of activity and effort needed by the consumer regarding that intent.

**Research Question 5**

Do consumers retain risk information from advertisements for prescription drug products?

In research question 5, as another measure of advertising effectiveness, the researcher measured retention of risk information from the advertisement for Hytrin<sup>R</sup>. Ten
true/false statements were given to the respondent to answer. Five questions were from the information contained within the ad and five from the brief summary.

Chi-square analysis showed no difference among the three treatment groups regarding the number of questions answered correctly, incorrectly, or did not know the answer. In fact for most questions, upwards of 90% of the respondents in each of the three groups answered they did not know the answer to the question (see Table 37). Also, there was no significant difference among the groups in their ability to answer the question based on whether it was derived from information within the ad or information in the brief summary. When looking at the results in Table 37, the product specific ad group did answer slightly more of the questions correctly, but again this was not statistically significant.

Finally, composite scores for all ten risk information questions together were analyzed using analysis of variance. Respondents were given one point for a correct answer and no points for an incorrect or did not know answer. Again, there was no statistically significant difference among the
three groups based on this composite score (see Table 38). Therefore, it can be concluded that the intervention had no effect on the ability of the respondents to answer risk information questions correctly.

Another analysis was conducted on the same ten questions, but using two different independent variables to replace experimental group. The variables were whether the respondent had taken Hytrin\textsuperscript{R} in the past and whether the respondent had seen an ad for Hytrin\textsuperscript{R} in the last 3 months. Remember, in this study actual ads for Hytrin\textsuperscript{R} were used. The same ads used in the study as well as other Hytrin\textsuperscript{R} ads had been used in the past. This most likely accounts for some of the explanation for the control group and the institutional ad group answering some of the risk questions correctly. The ability of the respondent to guess correctly (50% chance) also may play a role.

The respondents were divided into one of four groups: 1) No, they had not taken Hytrin\textsuperscript{R} in the past and No, they had not seen an ad for Hytrin\textsuperscript{R} in the past, 2) No, they had not taken Hytrin\textsuperscript{R} in the past and Yes, they had seen an ad for Hytrin\textsuperscript{R} in the past, 3) Yes, they had taken Hytrin\textsuperscript{R} in
the past and No, they had not seen an ad for HytrinR in the past, and 4) Yes, they had taken HytrinR in the past and Yes, they had seen an ad for HytrinR in the past.

Chi-square analysis showed a significant difference among the four groups regarding the correct answering of all ten risk information questions (see Table 39). A higher percentage of respondents answered the questions correctly in the group that had seen an ad for HytrinR but had not taken HytrinR (column 2) versus the group that had not seen an ad for HytrinR nor taken HytrinR in the past. This shows that the recall of having seen an ad for product resulted in a higher percentage of the respondents answering the question correctly.

Further examination of the data shows that a larger percentage of respondents answered the questions correctly who had taken HytrinR in the past (columns 3 and 4) compared to those who have not (columns 1 and 2). This shows that experience in using the product does affect the amount of risk information retained. The group that had taken HytrinR may have received additional the risk information from the
physician, pharmacist, or PPI (Patient Package Information) leaflets distributed with many prescriptions.

The group that had not taken Hytrin® nor seen an ad answered “don’t know” greater than 96% of the time for all ten questions. This is compared to 62%-86% for the group that had seen an ad but had not taken Hytrin® and 29%-76% for the 2 groups that had taken Hytrin® in the past. This shows that seeing an ad for the product increases the confidence of the respondent to try to answer the risk questions and experience in using the product increases this confidence even more. There is, however, a downside to this perceived knowledge of risk information by the individual.

The group that had not taken Hytrin® nor seen an ad answered the questions incorrectly only 0%-3% of the time. The group that had seen and ad for Hytrin® but had not taken the product previously answered the questions incorrectly 0%-17% of the time compared to 6%-50% for the two groups that had taken Hytrin® in the past. This leads the researcher to believe that even though seeing the ad and past experience increases the percentage of respondents answering the risk information question correctly, these two
factors also increase the percentage of risk information questions answered incorrectly. Seeing an ad and previous experience with the advertised product may give the individual a false sense of knowledge regarding risk information.

An analysis of the composite score for all ten questions also was conducted for these four groups. One way analysis of variance showed that there was a significant difference among the four groups in their average composite scores regarding risk information retention (see Table 40). Seeing an ad and past experience in taking the product alone each significantly increased the average composite score of the respondents (as shown by post hoc analysis using LSD Test and Scheffe’s Test). But when seeing an ad and past experience in taking the product are combined, there is no significant difference observed between these respondents and those taking Hytrin® in the past and not seen an ad. Actually, we see a slight decrease in the average composite score of respondents who had taken Hytrin® and seen an ad.

Further examination of the composite scores is still somewhat disappointing. The average score for the group
that had not seen an ad nor taken Hytrin\textsuperscript{R} was 0.18. This means that for this group the average respondent got less than one question correct. For the group that had seen an ad but had not taken Hytrin\textsuperscript{R}, the average score was 1.42. This shows that the average consumer who had seen an ad still was able to answer less than two questions out of ten correctly.

When the past experience in taking the product is added, the average score jumps to about 3 questions answered correctly. This is still disappointing in only an average of 3 pieces of risk information are remembered by the patient even though pharmacist and doctor counseling should have occurred. The low score could be due to the patient not being able to recall risk information or that the pharmacist and physician are not providing risk information and the patient is relying solely on his own personal experience in using the drug. More research needs to be conducted to determine why patients are not retaining more risk information from the ads themselves and from information supposedly provided by the physician and pharmacist.
Some researchers may feel that only retaining enough risk information to be able to answer between one and two questions correctly out of ten is not viewed as successful in the retention of risk information. Some might argue that this is viewed as hardly remembering anything. However, I would tend to disagree with opinion.

DTCA has not evolved to the level of being consumer friendly or worded easy enough for consumers to understand the information presented in the ads. For this study, if the average consumer who saw an ad for Hytrin® in past remembered two pieces of risk information, I would say the ad was successful in conveying risk information. For a consumer to remember two pieces of risk information from a highly technical ad they may only be exposed to for a short time, I think, represents a significant accomplishment considering the bombardment of ads to which consumers are exposed. Others may argue that the two pieces consumers remember may not be the most important ones. I believe that this issue should be addressed by the social responsibility of the manufacturer who develops the ad.
It’s also important to know that the results of risk information retention for this ad are probably at the higher end of the spectrum. The Hytrin® ad used in this study was more consumer friendly, in the opinion of the researcher, when compared to other DTCA. Also, this ad incorporated a re-designed brief summary rewritten specially for the consumer. Most DTCA contains copies of the package insert given to pharmacists and physicians. Therefore, the results for this study of risk information retention are probably better that for most DTCA. The results of this part of the study may be limited in their generalizability of risk information to other DTCA.

The explanation for the different results of the two different analyses is easy to understand. The study respondents received the ads for Hytrin® through the mail. These respondents not only did not retain a significantly larger amount of risk information, but also the ad had no effect on attitudes, behavioral intent, and actual behavior. This finding leads further credibility to failure of the intervention.
When the respondents were stratified based on having seen an ad for Hytrin R and past experience in taking Hytrin R versus experimental group, a significant difference was observed in the retention of risk information. Respondents who had seen an ad for Hytrin R in the second analysis probably had seen or heard an ad somewhere else, either radio, television, newspaper or magazine. These respondents could have also had a significantly higher number of exposures than the three exposures from the product specific ad group. The important thing to consider is that the research shows that consumers who have seen an ad for Hytrin R in the past did retain some risk information. There is, however, a great amount of future research that needs to be done in this area.

The FDA views this area of research as important. What information consumers are processing from DTCA is important to know. Currently, the regulations regarding the balanced presentation of risk and benefits in an ad are broadly stated. Future research needs to be conducted on the ability of consumers to comprehend complex medical information presented in DTCA. Research also needs to be
conducted in the use of a consumer-friendly brief summary versus a copy of the package insert currently used in most DTCA and its affect on consumer retention and understanding of risk information. Also, are consumers easily misled by the information presented in DTCA? Finally, research needs to be conducted to determine exactly what consumers remember about the ads they see. Do they only remember the benefits of the advertised product or do they also remember risks as well?

Research in these areas, as well as others, will allow the FDA to appropriately regulate DTCA so that it serves the purpose of both the consumer and prescription drug manufacturer. I feel DTCA is an important tool to help educate consumers about prescription drugs and should be allowed. DTCA also fosters communication between the consumer and his/her physician or pharmacist. DTCA can stimulate consumers to take a more active role in their own health care by discussing what they’ve seen in ads with their physicians and/or pharmacist. When consumers take a more active role in their own health care, all of society could benefit through lower costs, more satisfied consumers,
increased productivity, and most importantly a more educated consumer.

**Implications for the Theory of Planned Behavior**

**Use of a Single Attitude Measure**

All three models developed by Fishbein and Ajzen, 1) Fishbein Model, 2) Theory of Reasoned Action (Extended Fishbein Model), and 3) Theory of Planned Behavior, all use a single attitude measure, attitude toward the product or attitude toward the behavior. This simplistic view may be appropriate for simple behaviors such as buying a candy bar or choosing a brand of soda. But for more complex behaviors, such as health care related behaviors which may not be under the direct control of the individual, more than one attitude may influence the final behavior. This theory of more than one attitude may be the reason for low proportion of variance explained in past studies than have used one of these models.
This study postulated that three different attitudes may affect the final behaviors of obtaining a prostate exam and obtaining a prescription for Hytrin\textsuperscript{R}. This postulation was based on previous research by Morris et al. (1986a and 1986b). Further evidence is provided by the regression analysis in Research Question 4. In Table 34, the attitude toward the product Hytrin\textsuperscript{R} and attitude toward asking the physician for a prescription for a specific product had negative Beta Coefficients while attitude toward DTCA was positive. In Table 35, the attitude toward the product Hytrin\textsuperscript{R} and the attitude toward DTCA had negative Beta Coefficients while attitude toward asking the physician for a prescription for a specific product was positive. Even though none of these attitudes measures contributed significantly to the total variance, the differences in signs (positive versus negative) and differences in coefficient values lends more evidence to support the theory of multiple attitude measures.

Future research, especially in the modeling of complex behaviors, should examine the possibility of multiple attitude constructs that may affect the behavior of
interest. Incorporating other attitudes that may affect behavior may increase the explanatory power of the model. More research needs to be conducted to properly answer the question raised by this study.

**Perceived Behavioral Control**

The addition of perceived behavioral control to the Fishbein and Ajzen models is relatively a new concept. One of the first published papers explaining the Theory of Planned Behavior only appeared about five years ago (Ajzen, 1991). Therefore a limited amount of research has been conducted using the model to predict and explain behaviors. Therefore many questions remain regarding its appropriate use.

Perceived behavioral control differs from other measures of control in one main regard. Ajzen believes that the amount of perceived control a consumer has is situation specific. This level or degree of control changes based on the situation and the behavior of interest. This theory is different from Rotter’s Perceived Locus of Control, for
example. Rotter believes that perceived locus of control is a generalized expectancy that remains stable across many different situations, actions, and behaviors (Rotter, 1964).

Another behavioral theory, Atkinson’s Theory of Achievement, is somewhat similar to Ajzen’s perceived behavioral control. In Atkinson’s Theory, the primary focus of perceived control is based on expectancy of success (Atkinson, 1964). This theory is similar to Ajzen’s, but the expectancy of success is not entirely situation specific. Atkinson’s theory lies between Rotter’s locus of control and Ajzen’s perceived behavioral control.

This study provided supporting evidence that Ajzen’s theory of perceived behavioral control is situation specific and that perceived control should be viewed as situation specific. In the regression analysis of Research Question 4, perceived behavioral control significantly contributed to the total variance explained (T-ratio = 5.38 and p-value = 0.0001) regarding the behavioral intent of asking the physician for a prostate exam (see Table 34). However, perceived behavioral control did not significantly contribute to the total variance explained (T-ratio = 1.18
and p-value = 0.24) regarding the behavioral intent of asking the physician for a prescription for Hytrin® if the prostate was enlarged.

These results make sense intuitively from a situation-specific perspective. The patients felt they have more control in obtaining a prostate exam (Standardized Beta Coefficient = 0.34) than obtaining a prescription for Hytrin® (Standardized Beta Coefficient = 0.07). The Beta Coefficient for obtaining a prescription for Hytrin® is expected to be lower than for obtaining a prostate exam. A patient probably believes they have more control over convincing a physician to give them a medical test or procedure as compared with being able to convince the physician to write a prescription for a specific product. Even though these results support the Ajzen’s construct of perceived behavioral control, there are some areas in which future research needs to be done.

Ajzen has struggled with how to properly measure the construct of perceived behavioral control. Ajzen and Madden (1986) identified several components that comprise and individual’s perceived behavioral control. These are
obligation, motivation, time, ability, and need of assistance. Each of these items are incorporated into a separate question. The items are then summed to give a summated score (multi-item measure) of the individual’s perceived behavioral control. Ajzen also suggested using a single item to measure perceived behavioral control. In some instances, a single item measure was more reliable than the multi-item measure (Ajzen, 1991).

For our study we used both single item and multi-item measures for each of the two behaviors of interest. We included four of the five components in our multi-item measure since the obligation component did not apply in this study. Reliability analysis showed that the multi-item measure of perceived behavioral control in obtaining a prostate exam was reliable (Coefficient alpha = 0.72). However, the multi-item measure for perceived behavioral control in obtaining a prescription for Hytrin® was not reliable (Coefficient alpha = 0.32). This is puzzling to the researcher since the same four components (time, ability, motivation, and need of assistance) were used in both measures. Only the behavior of interest or situation
was changed. Therefore, for the perceived behavioral control in obtaining a prescription for Hytrin® the single item measure was used.

These results further support Ajzen’s dilemma regarding whether to use a single or multiple item measure and in which situations each should be used. As more research is conducted using the Theory of Perceived Behavioral Control, resolution of the problem may become clearer. Future research therefore needs to address the following issues, some of which were mentioned by Ajzen, 1991:

1) When is it appropriate to use a single item measure?

2) When is it appropriate to use a multi-item measure?

3) Are there other components to the multi-item measure of perceived behavioral control other than the five mentioned by Ajzen and Madden (1986)?

4) Are there specific situations when only certain items from the five components mentioned by Ajzen and Madden (1986) should be used?
5) Does the complexity or degree of effort required of the behavior of interest affect which type of measure should be used?

The researcher believes that Ajzen’s perceived behavioral control is an important component in explaining and predicting behavior. However, some of the concerns raised above need to be addressed before the full usefulness of the model can be realized.

The Relationship Between Behavioral Intent and Behavior

When the original Fishbein Model was proposed, much of it’s usefulness was derived from the behavioral intent component of the model. Most market research, even today, uses the surrogate endpoint of behavioral intent as the final outcome measure. This is done for a simple reason. Many times the researcher cannot measure or be with the consumer when the actual behavior is exhibited. Therefore, behavioral intent is used as a proxy measure of actual behavior.
The measurement of behavioral intent allows the researcher to study the affect of interventions in an artificial setting without following the consumer and observing what they actually do. For example, if the researcher shows a consumer a series of ads (including one for Snickers) for candy bars and the consumer says she intends to buy a Snickers candy bar next time she wants chocolate, the researcher might conclude the ad was effective. This is an over-simplified situation, but illustrates how market research and consumer behavior relies on behavioral intent in many cases as the final outcome.

Past research has shown that behavioral intent is correlated with actual behavior (Ajzen, 1991). For many behaviors, this may be true. But I contend that for complex behaviors, behaviors that require a great deal of effort or steps for the consumer to take to exhibit that behavior, this assumed strong correlational relationship may not be present. I would argue that if a consumer says they intend to buy Pepsi the next time they are faced with a soda choice they may. But my research on obtaining a specific prescription drug product shows the contrary.
In Chapter 4, Research Question 4, Point biserial correlations were calculated between the behavioral intent and actual behavior and the predicted behavioral intent from the model and actual behavioral intent. For model #1 (Figure 6) the behavioral intent studied was asking the physician for a prostate exam at the next scheduled appointment. The Point biserial correlation between the behavioral intent and actual behavior was statistically significant (Point biserial = 0.22 and p-value = 0.0001). The correlation between the predicted behavioral intent and actual behavior was even higher (Point biserial correlation = 0.34 and p-value = 0.0001). This shows there is a statistically significant correlation between the behavioral intent and actual behavior, albeit a small one. Logistic regression also showed that behavioral intent was a statistically significant predictor of actual behavioral (p value = 0.0013).

For model #2 (see Figure 7), the behavioral intent studied was making a special appointment to see the physician and ask for a prostate exam. The Point biserial correlation between the behavioral intent and actual
behavior was statistically significant (Point biserial correlation = 0.23 and p-value = 0.001). The correlation between the predicted behavioral intent and actual behavior was even higher (Point biserial correlation = 0.31 and p-value = 0.0001). This shows there is a statistically significant correlation between the behavioral intent and actual behavior, again albeit a small one. Logistic regression also showed that behavioral intent was a statistically significant predictor of actual behavioral (p value = 0.0006). We see different results for the third model.

In the third model (Figure 8), the behavioral intent studied asked the patient if they would ask their doctor for a prescription for Hytrin® if a prostate exam showed the prostate was enlarged and treatment was needed. The Point biserial correlation between the behavioral intent and actual behavior was not statistically significant (Point biserial correlation = 0.08 and p-value = 0.24). The correlation between the predicted behavioral intent and actual behavior was even smaller (Point biserial correlation = 0.05 and p-value = 0.47). This showed there was not a
statistically significant correlation between the behavioral intent and actual behavior. Logistic regression showed that behavioral intent was a not statistically significant predictor of actual behavioral (p value = 0.24). This finding raises serious questions regarding the use of behavioral intent as a surrogate endpoint or proxy measure of behavior.

These results show that as the steps needed to exhibit a given behavior increase, the correlation between the behavioral intent and the actual behavior decreases. This is an important finding since many research studies use behavioral intent as the final measure. Future research needs to be conducted to determine when, under what circumstances, and which types of behaviors is the behavioral intent not correlated with the final behavior. In health care studies, such as this one, caution should be used when behavioral intent is used as the defining factor as to whether an intervention or treatment is effective.
Limitations of the Study

The results from this study should be interpreted with the limitations of the research in mind. The respondents in the study were males between the ages of 60 and 75, except for three outliers. They were Ohio residents selected randomly from a mailing list pool of AmericaList Inc. The ads used in the study were a prostate (BPH) education ad and product specific ad for Hytrin®, a treatment approved for BPH. Therefore any conclusions of the study are limited to that of the study group. Any generalizations to other groups are only appropriate to the extent that the group is represented by the respondents.

Also, the results presented in this study are for ads for BPH and Hytrin®. The effects of these ads on patient’s attitudes, subjective norms, perceived behavioral control, behavioral intent, and actual behavior cannot be generalized to other prescription drugs, product classes, or institutional ads advertised directly to consumers. Finally, the medium chosen to deliver the DTCA was direct mail. Other forms of DTCA, radio, television, newspapers,
magazines, may yield different results regarding effectiveness.
APPENDIX A:

ADVERTISEMENT FOR HYTRIN®
Every man over 50 should take this PROSTATE TEST

Please answer the following questions:

YES  NO

☐ ☐ Do you urinate often, especially during the night?

☐ ☐ Do you have trouble starting your urine stream?

☐ ☐ Do you have a weak or interrupted urine stream?

☐ ☐ Does it feel like your bladder isn’t emptying completely?

If you answered yes to any question, you should see your doctor.
You may be experiencing the symptoms of a condition called benign prostatic hyperplasia (BPH), which is an enlargement of the prostate gland.

Affecting one out of three men over the age of 50, symptomatic BPH can be caused by a tightening of muscles inside the prostate. These tightened muscles can slow the flow of urine, leading to the kinds of urinary symptoms described above.

There are three basic treatment options for symptomatic BPH:

- "Watchful waiting," which entails having regular checkups over time, surgery, and medication.

HYTRIN: A New Treatment Option

HYTRIN is a once-daily medication that can safely treat bothersome BPH symptoms. HYTRIN works by relaxing the muscles that have tightened in the prostate, increasing urine flow and decreasing urinary symptoms. With HYTRIN, you may see improvement in 2 to 4 weeks.

HYTRIN can cause a sudden drop in blood pressure at the beginning of treatment (or if you miss doses and then start taking the medication again). You may feel dizzy, faint, or "light-headed," particularly after getting up from a chair or bed.

Ask your doctor if HYTRIN is right for you.

If you have any urinary symptoms, see your doctor. Your doctor can properly diagnose symptomatic BPH for other conditions such as prostate cancer.

Please see patient information on adjacent page.

© 1994 Abbott Laboratories

ASK YOUR DOCTOR TODAY ABOUT HYTRIN

(Start Page)
HYTRIN
(terazosin HCl)

PATIENT INFORMATION
ABOUT
HYTRIN® (HI-TRIN)

Generic Name:

terazosin (ter-A-zo-sin)
hydrochloride

When used to treat
BENIGN PROSTATIC HYPERPLASIA (BPH)

Please read this leaflet before you start taking HYTRIN. Also, read it each time you get a new prescription. This information should NOT take the place of a full discussion with your doctor. You and your doctor should discuss HYTRIN and your condition before you start taking it and at your regular check-ups.

HYTRIN is used to treat benign prostatic hyperplasia (BPH). HYTRIN is also used to treat high blood pressure (hypertension). This leaflet describes HYTRIN only as a treatment for BPH.

What is BPH?

The prostate is a gland located below the bladder. It surrounds the urethra (you-RET-hrah), which is a tube that carries urine from the bladder. BPH is an enlargement of the prostate gland. The symptoms of BPH, however, can be caused by an increase in the tightness of muscles in the prostate. If the muscles inside the prostate tighten, they can squeeze the urethra and slow the flow of urine. This can lead to symptoms such as:

• a weak or interrupted stream when urinating
• a feeling that you cannot empty your bladder completely
• a feeling of delay when you start to urinate
• a need to urinate often, especially at night, or
• a feeling that you must urinate right away.

Treatment options for BPH

There are three main treatment options for BPH:

• Program of monitoring or "Watchful Waiting". Some men have an enlarged prostate gland, but no symptoms, or symptoms that are not bothersome. If this applies, your doctor may decide on a program of monitoring including regular check-ups, instead of medication or surgery.

• Medication. There are different kinds of medicines that are used to treat BPH. Your doctor has prescribed HYTRIN for you. See "What HYTRIN does" below.

• Surgery. Some patients may need surgery. Your doctor or surgeon can describe different surgical procedures to treat BPH. Which procedure is best depends on your symptoms and medical condition.

What HYTRIN does

HYTRIN relaxes the tightness of certain types of muscle in the prostate and at the opening of the bladder. This may increase the ease of urine flow and decrease the symptoms you are having.

• HYTRIN helps relieve the symptoms of BPH. It does NOT change the size of the prostate, which may continue to grow. However, a larger prostate does not necessarily cause more or worse symptoms.

• If HYTRIN is helping you, you should notice an effect on your particular symptoms in 2 to 4 weeks of starting to take the medication.

• Even though you take HYTRIN and it may help you, HYTRIN may not prevent the need for surgery in the future.

What you should know while taking HYTRIN for BPH

WARNINGS

HYTRIN Can Cause A Sudden Drop in Blood Pressure After The VERY FIRST DOSE. You may feel dizzy, faint, or "light-headed" particularly after you get up from bed or from a chair. This is more likely to occur after you've taken the first few doses, but can occur at any time while you are taking the drug. It can also occur if you stop taking the drug and then re-start treatment.

Because of this effect, your doctor may have told you to take HYTRIN at bedtime. If you take HYTRIN at bedtime but need to get up from bed to go to the bathroom, get up slowly and cautiously until you are sure how the medicine affects you. It is also important to get up slowly from a chair or bed at any time until you know how you react to HYTRIN. You should not drive or do any hazardous tasks until you are used to the effects of the medication. If you begin to feel dizzy or sit down until you feel better.

• You will start with a 1 mg dose of HYTRIN. Then the dose will be increased as your body gets used to the effect of the medication.

• Other side effects could be:

  - Dizziness, blurriness, nausea, or "pressure" of the first few doses. Discuss any unexpected effects you notice with your doctor.

Other important facts

• You should see an effect on your symptoms in 2 to 4 weeks. So, you will need to continue seeing your doctor to check your progress regarding your BPH and to monitor your blood pressure in addition to your regular check-ups.

• Your doctor has prescribed HYTRIN for your BPH and not for prostate cancer. However, a man can have BPH and prostate cancer at the same time. Doctors usually recommend that men be checked for prostate cancer once a year when they turn 50 (or 40 if a family member has had prostate cancer). These checks should continue even if you are taking HYTRIN. HYTRIN is not a treatment for prostate cancer.

• About Prostate Specific Antigen (PSA). Your doctor may have done a blood test called PSA. Your doctor is aware that HYTRIN does not affect PSA levels. You may want to ask your doctor more about this if you have had a PSA test done.

How to take HYTRIN

Follow your doctor's instructions about how to take HYTRIN. You must take it every day at the dose prescribed. Tell your doctor if you don't take it for a few days, you may have to restart it at a 1 mg dose and be cautious about possible dizziness. Do not share HYTRIN with anyone else; it was prescribed only for you.

Keep HYTRIN and all medicines out of the reach of children.

FOR MORE INFORMATION ABOUT HYTRIN AND BPH TALK WITH YOUR DOCTOR, NURSE, PHARMACIST OR OTHER HEALTH CARE PROVIDER.

Ref: 01-4458-R-1-Revised Sept., 1993

ABBOTT LABORATORIES
North Chicago, IL 60064
PRINTED IN U.S.A.

(Back Page)
APPENDIX B:

DISEASE SPECIFIC INSTITUTIONAL ADVERTISEMENT FOR BPH
EVERY MAN OVER 50 SHOULD TAKE THIS PROSTATE TEST

Please answer the following questions:

1) Do you urinate often, especially during the night?

2) Do you have trouble starting your urine stream?

3) Do you have a weak or interrupted urine stream?

4) Does it feel like your bladder isn’t emptying completely?

If you answered “yes” to any question, you should see your doctor. You may be experiencing the symptoms of a condition known as benign prostatic hyperplasia (BPH), which is an enlargement of the prostate gland. BPH affects 1 out of every 3 men over the age of 50. BPH is usually caused by the tightening of the muscles of an enlarged prostate.

**Symptoms of BPH (enlarged prostate)**

Commonly occurring symptoms of BPH are more frequent urination, sudden or uncontrollable urge to urinate (especially at night), a weak or interrupted urine stream, or a sense of the bladder not emptying completely, leakage, or a feeling of difficulty in starting a stream.

**Your Doctor Can Help**

Your doctor now has several treatment options to help you with this problem. Recent medical advances have made this possible. So now, more than ever, is an excellent time to consult your doctor. If you are experiencing any of these symptoms, or answered “yes” to one or more of the above questions, see your doctor and speak openly about this problem. It’s important to you and your family that you do.
APPENDIX C:

RESEARCH SURVEY INSTRUMENTS
**SECTION 1**

**Directions.** Write in the number which best describes your disagreement or agreement with each of the following statements regarding your attitude towards advertising prescription drugs directly to consumers in magazines, newspapers, direct mail and TV.

<table>
<thead>
<tr>
<th>Strongly Disagree</th>
<th>Moderately Disagree</th>
<th>Slightly Disagree</th>
<th>Neither</th>
<th>Slightly Agree</th>
<th>Moderately Agree</th>
<th>Strongly Agree</th>
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Here is an Example:

- 6  Prescription drugs are beneficial.
- 4  Prescription drugs are priced too high.

The individual indicated he/she moderately agrees (6) that prescription drugs are beneficial and neither disagrees or agrees (4) that prescription drugs are priced too high.

Please use the same scale to indicate your level of disagreement or agreement with each of the following statements.

______ a) I would like to see more advertisements for prescription drugs.

______ b) Most people would be able to tell if they were being misled in an ad for a prescription drug.

______ c) Only a physician can tell if an ad for a prescription drug is truthful or not.

______ d) Advertising prescription drugs directly to consumers will benefit consumers.

______ e) Prescription drugs should not be advertised directly to consumers.

______ f) Prescription drug ads provide useful information to consumers.

______ g) Prescription drug advertising to consumers causes drug prices to go up.

______ h) If a prescription drug is advertised to consumers, it must be safe to use.

______ i) Most patients can tell if a prescription drug should or should not be used.
j) Prescription drug information should only come from your doctor or pharmacist.

k) Prescription drugs for serious medical problems should not be advertised to consumers.

l) I think consumer advertisements for prescription drugs would provide consumers with information they have a right to know.

m) Prescription drug advertisements are a reliable source of drug information.

n) The government should regulate advertisements of prescription drugs that are targeted towards consumers.

o) If I asked my doctor to prescribe a specific drug for me and he/she refused, I would be upset with my doctor for refusing my request.

p) If I asked my doctor to prescribe a specific drug for me and he/she refused, I would go to another doctor with my request.

q) If I asked my doctor to prescribe a specific drug for me and he/she refused, I would follow his/her advice.

r) If I asked my doctor to prescribe a specific drug for me and he/she refused, I would be upset with myself for asking for a specific drug.
SECTION 2

Have you ever heard of the drug Hytrin which is used to treat an enlarged prostate, also known as Benign Prostatic Hyperplasia (BPH)? Please answer yes or no.

____ No, I have not heard of Hytrin. (Skip to SECTION 3)

____ Yes, I have heard of Hytrin. (Please, finish the rest of SECTION 2)

Directions. Write in the number which best describes your disagreement or agreement with each of the following statements regarding the product Hytrin which can be used to treat the symptoms of an enlarged prostate.

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<th>Strongly Disagree</th>
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____ a) Hytrin is a very safe drug.

____ b) Hytrin is a very effective drug.

____ c) Overall, the benefits of using Hytrin outweigh the risks.

____ d) I would rather take other drugs than Hytrin for an enlarged prostate.

____ e) I would use Hytrin if my doctor prescribed it for me.

____ f) I would ask my doctor for more information about Hytrin.

____ g) I would ask my doctor's opinion on Hytrin.

____ h) An enlarged prostate is a serious disease.

____ i) It is worth risking side effects of drugs in order to treat an enlarged prostate.

____ j) Hytrin will work better than other treatments for an enlarged prostate.

____ k) Hytrin should be very effective in treating an enlarged prostate.

____ l) In general, Hytrin is the most successful way to treat an enlarged prostate.

____ m) I would feel comfortable asking my doctor to prescribe Hytrin for me if I developed an enlarged prostate.
### SECTION 3

**Directions.** Write in the number which best describes your disagreement or agreement with each of the following statements.

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<th></th>
<th>Strongly Disagree</th>
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<th>Moderate or Agree</th>
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___ a) Generally speaking, my doctor thinks I should have a prostate exam.

___ b) Generally speaking, my family thinks I should have a prostate exam.

___ c) Generally speaking, my good friends think I should have a prostate exam.

___ d) Generally speaking, my pharmacist thinks I should have a prostate exam.

___ e) Generally speaking, I want to do what my doctor thinks I should do.

___ f) Generally speaking, I want to do what my family thinks I should do.

___ g) Generally speaking, I want to do what my good friends think I should do.

___ h) Generally speaking, I want to do what my pharmacist thinks I should do.

___ i) Generally speaking, my family thinks I should ask my doctor for a prescription for Hytrin if I develop an enlarged prostate.

___ j) Generally speaking, my good friends think I should ask my doctor for a prescription for Hytrin if I develop an enlarged prostate.

___ k) Generally speaking, my pharmacist thinks I should ask my doctor for a prescription for Hytrin if I develop an enlarged prostate.

___ l) Generally speaking, my doctor thinks I should ask him/her for a prescription for Hytrin if I develop an enlarged prostate.
SECTION 4

Directions. Write in the number which best describes your disagreement or agreement with each of the following statements.

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<th>Strongly Disagree</th>
<th>Moderately Disagree</th>
<th>Slightly Disagree</th>
<th>Neither</th>
<th>Slightly Agree</th>
<th>Moderately Agree</th>
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_______ a) I have the ability to convince my doctor to give me a prostate exam.

_______ b) I am motivated to ask my doctor to give me a prostate exam.

_______ c) I have the time to see my doctor for a prostate exam.

_______ d) I would need assistance in convincing my doctor to give me a prostate exam.

_______ e) I have the ability to convince my doctor to write a prescription for Hytrin if I wanted to.

_______ f) I am motivated to ask my doctor to write a prescription for Hytrin if my prostate exam showed my prostate was enlarged.

_______ g) I have the time to see my doctor and discuss treating an enlarged prostate.

_______ h) I would need assistance in convincing my doctor to write a prescription for Hytrin.

_______ i) I could convince my doctor to give me a prostate exam if I wanted to.

_______ j) I would have very little control in obtaining a prescription for Hytrin if I developed an enlarged prostate.

_______ k) If I wanted to, I could easily obtain a prescription for Hytrin from my doctor.
SECTION 5

Directions. Write in the number which best describes your disagreement or agreement with each of the following statements.

<table>
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<th>Strongly Disagree</th>
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a) I may have some of the symptoms of an enlarged prostate, also known as Benign Prostatic Hyperplasia (BPH).

b) I intend to ask my doctor to give me a prostate exam at my next scheduled appointment.

c) I intend to make a special appointment to see my doctor and ask him/her to give me a prostate exam.

d) I intend to ask my pharmacist about whether I should have a prostate exam.

e) If a prostate exam showed my prostate was enlarged and I needed treatment, I would ask my doctor for a prescription for Hytrin.

Additional Comments

Directions. If there are any additional comments you would like to make about the product Hytrin or advertising prescription drugs to consumers, please write them in the space provided below. If you need more room, use the back page of this questionnaire.
SECTION 6

Directions. Based on your knowledge of Hytrin, please circle True (T), False (F), or Don't Know (DK) for each of the following statements.

T  F  DK  a) Hytrin can cause a sudden drop in blood pressure at the beginning of treatment.
T  F  DK  b) Hytrin can cause a sudden rise in blood pressure at the beginning of treatment.
T  F  DK  c) If you miss doses and then start taking Hytrin again, you may feel dizzy, faint, or "lightheaded".
T  F  DK  d) Patients with kidney or liver diseases should not take Hytrin.
T  F  DK  e) Hytrin may cause blurred or hazy vision as a side effect.
T  F  DK  f) Hytrin may cause impotence as a side effect.
T  F  DK  g) Hytrin may cause constipation as a side effect.
T  F  DK  h) Hytrin may cause drowsiness as a side effect.
T  F  DK  i) Hytrin may cause headaches as a side effect.
T  F  DK  j) Hytrin may cause "puffiness" of the feet and hands as a side effect.

Directions. Please answer the following questions about yourself.

Have you used any of the following treatments in the past to treat a prostate problem? (Circle all that apply)

a) THE PRESCRIPTION DRUG PROSCAR
b) THE PRESCRIPTION DRUG HYTRIN
c) OTHER PRESCRIPTION DRUGS
d) SURGERY
e) NONE OF THE ABOVE

Have you seen any advertisements for any of the following prescription drug products within the last 3 months? (Circle all that apply)

a) HYTRIN
b) PROSCAR
c) GLUCOTROL
d) LASIX
e) NONE OF THE ABOVE
What is your current marital status? (Please circle one)

a) MARRIED
b) DIVORCED
c) SEPARATED
d) WIDOWED
c) NEVER MARRIED

What is your highest level of education? (Please circle one)

a) ELEMENTARY SCHOOL
b) SOME HIGH SCHOOL
c) HIGH SCHOOL DIPLOMA OR EQUIVALENT
d) SOME COLLEGE
e) 2-YEAR COLLEGE DEGREE
f) 4-YEAR COLLEGE DEGREE
g) SOME GRADUATE WORK
h) GRADUATE DEGREE

Where do you live? (Please circle one)

a) LARGE CITY (OVER 100,000)
b) CITY (50,000-100,000)
c) SMALL CITY (10,000-49,999)
d) TOWN (2,500-9,999)
e) SMALL TOWN (UNDER 2,500)
f) RURAL

What is your annual household income? (Please circle one)

a) $0-$9,999
b) $10,000-$19,999
c) $20,000-$29,999
d) $30,000-$39,999
e) $40,000-$49,999
f) $50,000 AND ABOVE

What is your age? (Please circle one)

a) UNDER 50 YEARS OLD
b) 50 TO 59 YEARS OLD
c) 60 TO 75 YEARS OLD
d) 76 YEARS OLD OR OLDER
THE OHIO STATE UNIVERSITY THANKS YOU FOR YOUR TIME AND COOPERATION. PLEASE PLACE THE QUESTIONNAIRE IN THE POSTAGE PAID RETURN ENVELOPE PROVIDED.
A CONSUMER SURVEY OF  
HEALTH BEHAVIORS

Directions. Please answer the following questions about yourself. You may circle more than one answer for questions 2 and 3.

1) Have you been to see a doctor in the past 5 months?
   a) Yes
   b) No

2) Have you asked your doctor to perform any of the following tests or procedures on you in the past 5 months? (Circle all that apply).
   a) a blood pressure test
   b) a cholesterol test
   c) a prostate exam
   d) a blood sugar test
   e) a stress test

3) Have you had a new prescription filled for any of these products within the last 5 months? (Circle all that apply).
   a) Hytrin
   b) Vasotec
   c) Cardura
   d) Penicillin
   e) Proscar
   f) Zantac

THE OHIO STATE UNIVERSITY COLLEGE OF PHARMACY THANKS YOU FOR YOUR TIME AND COOPERATION. PLEASE PLACE THIS SURVEY IN THE POSTAGE PAID RETURN ENVELOPE PROVIDED.
APPENDIX D:

COVER LETTERS
July 1995

Dear Sir:

Important changes have been taking place in how prescription drugs are advertised. Drug companies are now advertising a large number of prescription drugs directly to consumers in newspapers, magazines, on television, and through direct mail. YOUR HELP IS NEEDED AND YOUR RESPONSES ARE VALUABLE. We would like to learn about your experiences and opinions regarding the advertising of prescription drugs directly to consumers.

You are one of a select group that has been randomly chosen to participate. Because only a small group was selected, we need everyone to respond. Please, help us by completing the enclosed questionnaire, even if you know nothing about the drug Hytrin. We know that this information may be personal and sensitive, therefore your responses will remain completely anonymous and confidential. We would ask that only male consumers over the age of 50 complete this questionnaire. This study will help educate other health care professionals on how consumers feel about being exposed to prescription drug advertising.

Please take about 15 minutes to complete the enclosed questionnaire and return it to us in the postage paid envelope we have provided within two weeks. A certified sportsfan certificate is enclosed as a gift to you for completing the questionnaire.

Thank you very much for completing this survey. This questionnaire is required for my Ph.D. degree in pharmacy. Your cooperation is valued and greatly appreciated.

Sincerely yours,

Donald L. Sullivan R.Ph. M.S.
Ph.D. Candidate at The Ohio State
University College of Pharmacy

Stephen W. Birdwell Ph.D.
Associate Professor at The Ohio State
University College of Pharmacy
August 1995

Dear Sir:

Recently you should have received a questionnaire concerning your experiences and opinions regarding the advertising of prescription drugs directly to consumers. If you have already completed and returned your questionnaire, thank you. If you have not received the questionnaire or have misplaced it, another one is enclosed. Please help us by taking about 15 minutes to complete the enclosed questionnaire and return it to us in the postage paid envelope we have provided within two weeks. Because only a small group was selected, your responses are desperately needed. **We know that this information may be personal and sensitive, therefore your responses will remain completely anonymous and confidential.**

Your assistance is greatly appreciated.

Sincerely yours,

Donald L. Sullivan R.Ph. M.S.
Ph.D. Candidate at The Ohio State University College of Pharmacy

Stephen W. Birdwell Ph.D.
Associate Professor at The Ohio State University College of Pharmacy
November 1995

Dear Sir:

Important changes are taking place regarding the types of health and wellness programs provided to patients. **YOUR HELP IS NEEDED AND YOUR RESPONSES ARE VALUABLE.** We would like to learn about your experiences regarding various health behaviors.

You are one of a select group that has been randomly chosen to participate. Because only a small group was selected, **we need everyone to respond.** Please, help us by completing the enclosed questionnaire. **We know that this information may be personal and sensitive, therefore your responses will remain completely anonymous and confidential.** Please take about 5 minutes to complete the enclosed questionnaire and return it to us in the postage paid envelope we have provided within two weeks.

Thank you very much for completing this survey. This questionnaire is part of the research required for my degree in pharmacy. Your cooperation is valued and greatly appreciated.

Sincerely yours,

Donald L. Sullivan R.Ph. M.S.
Ph.D. Candidate at The Ohio State University College of Pharmacy
December 1995

Dear Sir:

Recently you should have received a questionnaire concerning health behaviors. If you have already completed and returned your questionnaire, thank you. If you have not received the questionnaire or have misplaced it, another one is enclosed. Please help us by taking about 2 minutes to complete the enclosed questionnaire and return it to us in the postage paid envelope we have provided within two weeks. Because only a small group was selected, your responses are desperately needed. Your responses will remain completely anonymous and confidential.

Your assistance is greatly appreciated.

Sincerely yours,

Donald L. Sullivan R.Ph. M.S.
Ph.D. Candidate at The Ohio State University College of Pharmacy
LIST OF REFERENCES


