ANTECEDENTS OF DRUG REQUESTING BEHAVIOR

by

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(Under the Direction of MATTHEW PERRI III)

ABSTRACT

Consumers, as patients want to play a more active role in their healthcare. The growth in direct-to-consumer (DTC) advertising of prescription drugs has increased consumers' awareness of drugs resulting in increased prescription requests from physicians. This study examines the psycho-social antecedents of consumers' drug requesting behavior.

Using the Theory of Reasoned Action (TRA), our study demonstrated that consumers' attitudes and subjective norms are important in shaping their intentions of requesting an advertised drug. Consumers formulate subjective norms after processing the perceived beliefs of their referent group. Consumers also make inferences about subjective norms of their referent groups on the basis of their own beliefs and attitudes.

In addition to the attitudinal factors of TRA this research illustrates significant influence of consumers past behavior and trust in physician on their intentions to request a drug. Prior interaction between consumers and physicians motivates consumers to initiate a conversation with a physician about the advertised drug. This study provides evidences that consumers will not make bothersome requests about a prescription if they trust their physician.

This research also supports the multidimensional nature of attitudes. Consumers use rationale and judgment to process relevant information and arrive at cognitive evaluation of the attitude object – known as evaluative attitude. They also generate emotive responses, feelings, and thoughts in relation to the attitude object – known as affective attitude. These two components are distinct but correlated.

The study also highlights that DTC ads change consumers' beliefs and attitudes by two mechanisms. In the belief-based process of persuasion, consumer's process information contained about the product in the ad and use reasoning and judgment to form attitudes. In the non-belief based route of persuasion the influence of affect, generated after seeing an ad, creates favorable affective attitudes towards requesting the drug.

INDEX WORDS: DTC advertising, High cholesterol, Cognitive and affective routes of persuasion, Prescription drugs, Theory of reasoned action, Past behavior, Habit, Trust in physician, Structural equation modeling.

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DEDICATION

To my mother and father.

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TABLE OF CONTENTS

Page

CHAPTER 1

INTRODUCTION

In the past, physicians wrote prescriptions in Latin and handed them over to their patients. This was done to keep some mystery in the mind of the patients about the medicines / treatments they were getting. Patients had little say in the medical decision-making process. This 'paternalistic' model (Emanuel and Emanuel, 1992) characterized the dominance of the physician as a decision maker in the diagnosis and treatment of patients.

This form of medical decision-making has undergone considerable change. The American Medical Association (AMA, 1994) report on ethics underscores patient's rights in decision-making. It states that "…..*the patient has the right to make decisions regarding the health care that is recommended by his or her physician. Accordingly, patients may accept or refuse any recommended medical treatment*". The genesis of these rights can be attributed to the early 70's, when patients started getting more involved with their health care (Kasteler, Kane, Olsen, and Thetford, 1976). Research has also shown that patients believe they have a right to be involved in decisions about their medical care (Brody, Miller, Lerman, Smith, and Caputo, 1989).

These trends have changed the way in which treatments are now selected for patients. Decision-making is now focused on mutual participation in managing disease. Consumers, as patients, initiate conversation with their physicians. They inquire about their medical condition and want more information about various treatment options.

Further, they scrutinize these options in terms of their cost, intensity, duration and impact on their lifestyle (Johanson, Larsson, Saljo, and Svardsudd, 1998). This information results in a much more informed consumer. This enhanced interest makes them want to play an active role in treatment selection.

This research will address patients' 'drug requesting behavior'. Understanding this 'drug requesting behavior' should provide useful insights in the patient-physician interaction. This behavior is one way by which patients can initiate conversation with their physician. They can gather additional information about a drug or confirm the information they already possess. By requesting a particular drug patients can also identify under-informed physicians and may decide to go 'doctor shopping' (Kasteler, Kane, Olsen and Thetford, 1976). The physician on the other hand can utilize this request in providing the patient with all relevant information. To this end, the physician can discuss the benefits and risks of the requested drug and / or the treatment, and can help the patient appreciate the medical intervention.

A growing body of research has demonstrated the influential role of patients' participation in a medical decision-making on their satisfaction, compliance and health outcomes. Studies (Cooper-Patrick, Gallo, Gonzales, Vu, Powe, Nelson, and Ford, 1999; Speedling and Rose, 1985) have shown that when decision-making is mutual and participatory, satisfaction amongst patients is significantly higher. In fact, Ende et al (Ende, Kazis, Ash, and Moskowitz, 1989) have reported that patients were less satisfied with medical care when they were less interested in making decisions. Physicians who viewed their relationships with patients as a partnership had more satisfied patients

(Anderson and Zimmerman, 1993). Thus satisfaction seems to be an important outcome when patients are involved in the medical decision-making process.

In an empirical study, Heszen-Klemens and Lapinska (1984) concluded that when interaction was mutual, patients complied with their physician's recommendations better, but was worse when the amount of advice given to patients was larger. It is believed that patients will be more involved in completing their treatment when they feel they are a part of the decision. A critical review of the literature points out that non-compliance can be traced to problems in communication between patients and their physicians. (DiMatteo and Lepper, 1998). Better health outcomes are observed among patients who ask questions, inquire about treatment options and express their preferences (Benbassat, Pilpel, and Tidhar, 1998). Against this background, it is asserted that drug requesting behavior can play a vital role in encouraging patient-physician interaction thereby leading to enhanced care.

This research focuses on the antecedents of patients' 'drug requesting behavior'. It is believed that understanding the determinants of this behavior can provide useful perspectives in shaping the behavior. Health care providers can use these insights in predicting how variations in these determinants can change patients' 'drug requesting behavior'. In the interest of patient satisfaction and compliance, knowledge of these antecedents can be helpful in encouraging this behavior.

This research will study the antecedents of patients' 'drug requesting behavior' in three stages. The first stage of the research will determine the effects of direct-to-consumer advertising (DTC) advertising on this behavior. The second stage studies the antecedents using the theory of reasoned action (Ajzen and Fishbein, 1980; Fishbein and

Ajzen, 1975). In the final stage the role of past behavior or habit and trust in physician is investigated to explain their use in predicting ‘drug requesting behavior’.

The report begins with a review of the literature on the antecedents of drug requesting behavior. Specific theories and empirical research will be discussed to identify areas that can be applied to the present study. Following this review is a section addressing the research questions and hypotheses. A rationale of their pertinence is also discussed. The next section contains operational definitions, study design and methods that address the research issues. The final section of the report discusses the results and conclusions, and ends with a note on limitations in the scope of this study, and future research.

CHAPTER 2

LITERATURE REVIEW

The intent of this chapter is to provide an overview of the various concepts that will be researched relating to patients' 'drug requesting behavior'. This chapter is divided into 5 major sections. The purpose of these sections is two fold. First, to present a detailed literature review of the research conducted in the field. And secondly, to identify gaps and their relevance to drug requesting behavior. Section 1 reviews research pertaining to DTC advertising. Section 2 demonstrates the mechanisms of attitude formation and change. The role of the relatively new concept of 'attitude towards the ad' in attitude formation is discussed in section 3. The Theory of Reasoned Action and its applications are presented in section 4. Finally research on trust and past behavior or habit is reviewed in section 5.

2.1. Direct-to-Consumer Advertising

The Food and Drug Administration (FDA) has been regulating the promotion of medical products since 1962 (Drug Amendments, 1962). The FDA was empowered to monitor and control all promotional activities by pharmaceutical companies. At that time pharmaceutical companies promoted their products only to the physicians with the help of medical representatives, sampling, direct mail, scientific conferences or symposia, medical journals etc. In the early 1980's, realizing patients growing involvement in health

care, pharmaceutical companies also started advertising prescription medications directly to consumers.

In general the FDA applied the same rules and guidelines used in the traditional promotion of prescription drugs to efforts aimed at DTC advertising. This required DTC ads to (i) present a 'fair balance' of the risk and benefit information about the advertised drug, (ii) not be false or misleading and (iii) contain a 'brief summary' of the drug. This brief summary had all the risk information as well as the indications for use from the approved labeling.

The brief summary requirement was a major deterrent for the pharmaceutical companies in terms of cost and time. The product-specific print ads increased cost due to the additional requirements of one to three pages to provide the brief summary information. Providing this information in 30 seconds commercials on television and radio was also not feasible. Nonetheless, pharmaceutical companies advertised directly to the consumers using other forms of DTC ads. These were disease-specific ads (Kessler and Pines, 1990), which did not mention a product by name, but encouraged consumers to seek medical attention; and reminder ads, which mentions just the name of the product without any other information.

Recognizing the difficulty of including a 'brief summary' the FDA issued draft guidelines in August 1997 (FDA, 1997) addressing the issue of 'adequate provision' without the necessity for DTC ads to include the lengthy 'brief summary' information. In lieu, the ads had to provide sources of additional information for consumers. These could be in the form of a toll-free number, reference to print ads, an internet website, or referring to physicians or pharmacists. However, the ads still had to include a 'major

statement' on the important risks associated with the drug. These draft guidelines were finalized in 1999.

As a result of these guidelines, there has been a rapid growth of DTC advertising. Spending on DTC promotional activity increased 16 fold since 1993 (IMS, 2000). In 2000, the total expenditure reached nearly $2.5 billion (figure 1). Promotion via television accounts for over 60% of the promotional spending ($ 1.6 billion).

These high levels of investments have specific objectives. These can be classified into two major categories: informational and commercial. The informational objectives comprise of educating consumers to enable them to make informed health care decisions. This includes making them aware of the signs & symptoms of a disease and to seek medical attention. DTC ads can inform consumers of new and improved therapies. They can also encourage consumers to undertake preventive health measures. Knowledge about their illness and medications can lead patients to discuss their medical issues with their physicians and pharmacists and comply with their directions. This could lead to better health outcomes.

A major commercial objective is to increase sales. This is indirectly achieved by encouraging consumers to use their products by encouraging them to ask their physician to prescribe it. The incentive for generating brand loyalty is helpful for chronic disease states like diabetes, asthma, arthritis, etc where patients have to take medicines for a long duration of time. Increasing brand awareness and encouraging patients to complete their treatments could also increase sales. DTC ads also help in reaching physicians directly and indirectly through consumers' request. By providing information on product quality,

DTC ads can foster preference towards their products, which can reflect in increased demand and prescriptions.

The following sections summarize research addressing the impact of DTC ads focusing on studies that primarily address their influence on consumers. The review will be done in five major areas; a) Awareness and Attitudes b) Educational value c) Source and Formats d) Appeals e) Persuasive effects and f) Economic.

2.1.1. Awareness and Attitudes

Research has shown that consumers' awareness of DTC ads is increasing. Recognizing the popularity of DTC ads Perri and Nelson (1987) conducted an exploratory analysis of consumers' awareness. They used aided recall technique to gauge consumers' awareness of five drug ads of which only one ad was for a prescription drug. They reported a 12% awareness rate for the Pneumovax® ad. Though the recall of the prescription drug ad was lower than the over-the-counter (OTC) drug ads, it should be noted that the prevalence of DTC ads in the late 80's was much lower as compared to the number of DTC ads today. Using discriminant analysis the authors found that older consumers were more aware of DTC ads. They reasoned that older consumers who were more concerned with their health may have attended to the ad thus increasing awareness in this group.

With the increase in DTC ads in the 90's, the awareness among consumers had also increased. More than 35% of the consumers reported having seen or heard a DTC ad (Alperstein and Peyrot, 1993). This awareness increased to 42% when their recall was aided with a specific ad. A recent study (Bell, Kravitz, and Wilkes, 1999) reports that

women are more aware of DTC ads than men. The mean awareness was 37% (aided recall of 10 DTC ads) with a range of 8 to 72%. They also identified predictors of awareness and found awareness was related to respondents prescription drug use, perceived health status, attitudes towards these ads and media.

A closer look at the literature suggests that most of the research studies have focused on assessing consumers' attitudes towards DTC ads. It has been observed that consumers who are aware of DTC ads have favorable attitudes towards these ads (Alperstein and Peyrot, 1993; Bell, Kravitz, and Wilkes, 1999). Early studies conducted in the late 80's (Perri and Dickson, 1987; Perri and Nelson, 1987) conclude that consumers have a favorable attitude and approve of DTC ads. They feel that these types of ads would provide useful health related information. The authors considered the moderating influence of demographic and personal characteristics on attitudes. Using multiple regression they observed that consumers had favorable attitudes towards the DTC ads if they had the medical condition for which the drug was advertised.

Using a telephone survey Alperstein and Peyrot (1993) concurred with the previous studies that consumers have a positive attitude towards DTC ads. From their random sample, 70% respondents believed that DTC ads have an educational value and only 28% felt that DTC ads could be confusing. However they did not believe that DTC ads would lead to lowering of drug prices. The authors noted that consumers with favorable attitudes had higher awareness levels, were regular prescription drug users and were more educated.

Studies have evaluated the factors that impact consumers' attitudes, and a majority of them have identified that the elderly have more positive attitudes towards

DTC ads (Morris, Brinberg, Klimberg, Millstein, and Rivera, 1986; Perrien, Roy, Guiot, and Bastin, 1998; Williams and Hensel, 1995). In contrast, Gonul et al (Gonul, Carter, and Wind, 2000) found that older consumers do not value these ads and instead tend to trust their physicians. They found that consumers with children and with chronic conditions favor DTC ads. A negative correlation was observed between education, self reported health status and attitudes (Perri and Dickson, 1987; Williams and Hensel, 1995). Television ads were found to produce more favorable attitudes than magazine ads (Morris, Brinberg, Klimberg, Millstein, and Rivera, 1986).

This review of attitudinal studies is generally indicative of the increasing awareness and favorable attitudes of consumers. The high frequency of exposure is translated into awareness. Consumers process information in these ads and form attitudes on various issues related to DTC ads. The next section reviews studies that have addressed the persuasive effects of DTC ads.

2.1.2. Educational Value

To explain the educational value of DTC ads, Bell et al (Bell, Wilkes, and Kravitz, 2000) used content analysis to examine whether DTC ads provided consumers with health related information. They specifically examined if these ads disseminated information about medical conditions and treatment. They observed that virtually all ads provided the name of the medical condition and about two-thirds described at least one symptom of the condition treated by the drug. DTC ads rarely provided information on prevalence of the disease. They also noted that one-third of the ads provided the drugs' mechanism of action and more than a quarter of the ads described behavioral changes and

alternative treatments for the medical condition. The authors concluded by stating that the educational value was low with an average educational index of 3.2 (max: 11; range: 1.0 to 7.3).

In a study about women's perception on DTC ads, Kahn (2001) found about half the respondents agreed that DTC ads greatly improved their knowledge of prescription drugs and about 25% were more likely to follow the dosing instructions. She reported that older consumers were more likely to find DTC ads difficult to understand. Her results were similar to Foley's (Foley, 2000) who also noted that elders were less likely to fully comprehend the information contents in a DTC ad.

In an attempt to understand how information in an ad contributes to consumers' perception of the advertised drug, Schommer et al (Schommer, Doucette, and Mehta, 1998) tested 'rote learning' of consumers after they were exposed to a DTC ad. They defined rote learning as the ability to sustain information by consumers immediately after viewing the ad and believed that this information was crucial in the learning process. Their results suggested that rote learning was good, since respondents recalled more than 60% of the test items correctly. However, they also found that presenting benefit and risk information simultaneously in an ad could pose problems in the learning process.

Morris and colleagues studied miscomprehensions about the advertised products due to television and magazine ads (Morris, Brinberg, Klimberg, Rivera, and Millstein, 1986). The authors found that inaccurate interpretation of ad messages resulted in mistaken impressions, ranging up to 14%. They attributed these mistaken beliefs to the graphical aspects of the ads and low consumer knowledge of medical products.

It can be inferred at best that DTC ads provide moderate educational value. There seem to be certain segments, especially elderly and consumers with less health related knowledge where these ads are relatively less effective. However, these ads appear to increase consumers' involvement in their health.

2.1.3. Source and Formats

Consumers' knowledge, attitudes and believability of DTC ads seem to be affected by media, message formats and amount of information used in the ads. Morris et al (Morris, Brinberg, and Plimpton, 1984) provided evidence that ads with differing amounts of risk and benefit information were interpreted differently. Using a controlled experiment they varied the amount of information in ads and assessed consumers' reactions. Ads containing more information had higher knowledge scores. Consumers focused either on the risk or benefit information depending on the type of the drug shown in the ad. The authors also manipulated the placement of this information and found its significant relationship on consumers' beliefs. Integrated formats increased the believability of the ads over ads that contained separated formats.

Tucker and Smith (1987) also found similar results about the effects of the amount of information contained in DTC ads. Their four ads of an influenza vaccine had the same promotional message, but differed on the format of warning information. Consumers judged ads with detailed format of warning information to be of highest information value when compared to the other formats. However, it was observed (Christensen, Ascione, and Bagozzi, 1997; Davis, 2000) that ads containing a greater

number of risk statements or more severe risk statements had significantly lower appeal and were viewed less favorably.

Following up on their results of the 1984 study, Morris et al (Morris, Brinberg, Klimberg, and Rivera, 1986) conducted an experiment and found differential effects of the specificity of information and the media used to convey this information. Television ads appeared to produce more favorable attitudes than magazine ads. Similarly ads containing general risk information produced more favorable attitudes than ads containing specific risk information. The authors discussed that magazine ads are self-paced and hence risk information is better comprehended as consumers think more about their implications while reading.

2.1.4. Appeals

Pharmaceutical companies have used the route of DTC promotion for certain product categories more than others. Roth (1996) used content analysis to decipher patterns in DTC print ads. He observed that DTC ads were more prominent for drugs indicated for chronic conditions like allergies, hypertension etc. Recent studies have confirmed these results (Bell, Kravitz, and Wilkes, 2000; Parker and Delene, 1998). Roth further observed the high usage of DTC ads in disease states that were relatively easy to understand for the lay consumer.

Pinto (2000) explored the appeals used in DTC ads to communicate information to consumers. Her analysis showed prominent presence of informational and emotional appeals. On examining the visual and text elements in print ads she classified the emotional appeals into subcategories. ‘Fear’ appeal was the most widely used emotional

appeal (43%), followed by ‘humor’ (31%), ‘guilt’ (8.6%) and ‘sex’ (8.6%). These appeals had a mix of visual and text components.

In a similar fashion Bell et al (Bell, Kravitz, and Wilkes, 2000) classified informational appeals in addition to emotional appeals. Their information appeal dimension consisted of effectiveness, ease of use and safety appeals. The most common appeals according to their classification were ‘effective’, ‘control of symptoms’, ‘innovativeness’, and ‘convenience’. On cross tabulating appeals by medical condition they found a significant association between them. They also evaluated the inducements used in these ads and noted that informational offers was the most frequent (35%) inducement, followed by monetary (17%) and patient support (3%) inducements.

One observation that stands out from the ‘appeals’ review is that DTC ads use both cognitive and affective appeals in their promotion. Combinations of these appeals vary according to the type of medical condition for which the drug is advertised. However, research is needed to understand the effectiveness of these appeals.

2.1.5. Persuasive Effects

In an early work Perri and Dickson (1987) also evaluated consumers’ reaction to DTC ads. Results from their survey indicated that DTC ads stimulated patients to inquire about the advertised drugs with their physicians. This inquiry was however only limited to the informational aspects about the drug. They also assessed predictors of this behavior and reported that patients with the medical condition were more likely to attend to the information in the ads, process it and exhibit overt behavior.

Various studies have documented behavioral reactions by consumers after processing DTC ads (Bell, Kravitz, and Wilkes, 1999; FDA, 1999; Slaughter, 1999, 2000). These behavioral reactions are either in the form of information search or prescription requests from their physicians. Morris et al (Morris, Brinberg, Klimberg, and Rivera, 1986) provide similar findings on predictors of drug inquiry behavior as reported by Perri and Dickson (1987). In addition to the medical condition they identified old age, gender (female), and watching television influenced consumers' drug inquiry.

In a recent study, Peyrot et al (Peyrot, Alperstein, Doren, and Poli, 1998) found similar demographic factors predict behavior except for age, which was not significant in their analysis. They noted that educated consumers were more likely to interact with their physicians. They explored the mediation of several variables on drug requesting behavior and found attitude partially mediated the impact of certain demographic variables.

To trace the sources of information acquisition, Williams and Hensel (1995) measured consumers' intention to ask a physician, pharmacist or a friend. Based on their analysis they observed that in general physicians were preferred over pharmacist for additional information. This inclination skewed towards pharmacist or a friend among consumers who had favorable attitudes towards DTC ads. The FDA study (FDA, 1999) reports other sources such as a reference book, the Internet or calling the 1-800 number as possible alternatives consumers exercise for acquiring more information.

2.1.6. Economic

There is a growing concern among critics about the increase in health care costs (Wilkes, Bell, and Kravitz, 2000) and inappropriate prescribing (Lipsky and Taylor,

1997) as a result of DTC advertising. To address these concerns Rosenthal and colleagues (Rosenthal, Berndt, Donahue, Frank, and Epstein, 2002) examined the trends in total promotional spending. Based on their analysis they argue that the 1997 guidelines was not the most important factor for increase in promotional expenditures. A closer look at their results reveals that after 1997 spending on television ads was considerably higher than print and other media ads. Interestingly DTC accounts for less than 16% of the total promotional spending by the pharmaceutical industry. More dollars (80%) are spent in promoting drugs to health care professionals. However the total promotional spend as a percentage of sales has averaged at 14% for the last 5 years.

To explain the effect of DTC ads on prescription drugs' gross margin Kopp (1996; Kopp and Sheffet, 1997) used dual-stage theory as a framework in their analysis. Using this theory they hypothesized that retail gross margins of DTC products will be lower than unadvertised products. They provided empirical evidence in support for their hypothesis. They believed, according to dual-stage theory, that DTC campaigns influences consumers to demand for particular brands of drugs. Successful DTC ads reduces the price elasticity of consumers who demand for advertised branded drug even though they are priced higher. This compels the retailers to stock the advertised brands and as retail competition increases they reduce their gross margins to remain competitive.

Basara (1996) demonstrated the effectiveness of DTC ads by analyzing growth in prescriptions written by physicians after a DTC campaign. Using time series analysis she verified her hypothesis that DTC advertising helps in generating new prescriptions written by physicians while the campaign was in effect. On discontinuation of the campaign there is a residual effect, which declines exponentially.

2.1.7. Issues in DTC Advertising Research

A review of the above studies leads to three important observations. Firstly, DTC ads have an effect on consumers by educating them, thereby changing their attitudes and behavior. There is a differential effect of these ads based on consumers' health related and demographic profile. Variation of these ads in terms of formats, source and information result in different perceptions about the ad, the drug, the medical condition and treatment. Secondly, DTC ads have some economic implications. It has resulted in lower gross margins and increased prescription volume and promotional expenditure.

Lastly, there exist gaps in the research literature. The mechanism of attitude change in consumers after they encounter a DTC ad is not clearly documented. The nature of information processing will provide useful insights in the way attitudes are formed or changed. There is a need for clarity in understanding the persuasiveness of DTC ads. Is there an underlying cognitive process whereby consumers encode the information in ads and form attitudes? Or are attitudes formed as a result of affective appeals in DTC ads? Further, do these attitude formation processes vary across product categories? And within a same product category do these processes vary across different types of consumers? Research in this area will help marketers to better design their advertising campaigns in order to effectively communicate information about their products and medical condition.

2.2. Attitude Formation and Change

The processes that lead to formation or changes in attitudes are presented. The relevance of these processes in the formation of consumers' attitudes to request a drug from their physician is discussed.

2.2.1. The Concept of Attitude

The concept of attitude has been studied as a unidimensional construct and has evolved into a complex multidimensional construct. There are various definitions of attitudes. Fishbein and Ajzen (1972) observed more than 500 operational definitions of attitude. They noted that the various operational definitions depended on the objective of the study. According to them attitude is '*a learned predisposition to respond in a consistently favorable or unfavorable manner with respect to a given object'.* The object could be a person, a group of people, an institution, a behavior etc.

The multi-component view conceptualizes attitude as a hierarchical model (Bagozzi, 1978; Breckler, 1984; Rosenberg and Hovland, 1960). In this model attitude is considered as a second order factor composed of three first-order factors. These cognitive, affective, and conative components are viewed as three distinguishable parts of attitude. The cognitive component represents beliefs, judgments or thoughts associated with an attribute object, a person, a group of people, an institution, or a behavior (McGuire, 1985). Breckler and Wiggins (1989) view the cognitive component as evaluate in nature since it refers to judgments about the object.

The affective or emotional component refers to the overall feeling of like or dislike about the object (Day, 1972). This component includes all emotions, moods,

feelings or drives about the object (Batra and Ray, 1986). The conative component represents the behavioral intentions or the overt behavior regarding the object.

2.2.2. Cognitive Process of Attitude Formation and Change

Persuasion studies have documented two explanations of attitude formation and change. The cognitive process of attitude formation is based on the premise that consumers use reason and systematic thinking in evaluating persuasive messages. In this process the message generates cognitive responses in consumers mind. These cognitive responses are evaluated, processes and categorized in an orderly manner to form or change the underlying cognitive structure. These changes in the cognitive structure lead to attitude formation or change.

The cognitive route of attitude formation have been supported by a number of belief based theories, like the expectancy-value models (Fishbein, 1963; Fishbein and Ajzen, 1975; Greenwald, 1968; Wright, 1973), information-processing model (McGuire, 1972), and the subjective probability model (Wyer, 1970). According to the expectancy-value models, consumers' attitudes are determined by their beliefs about the object and the evaluative implications of these beliefs. A change in attitude towards the object requires changing either the beliefs about the object or the evaluative aspects of these beliefs.

The information-processing model (McGuire, 1972) states that consumers decipher the persuasive information in a problem solving mode and analyze each argument in the message. Effective persuasion depends on the attention and comprehension of the persuasive arguments. Wyer's subjective probability model

emphasizes consumers' use of reason. Consumers assign subjective probabilities to the arguments in the message and compute their subjective relevance leading to attitude formation or change.

2.2.3. Affective Process of Attitude Formation and Change

The alternative route of attitude formation and change is referred to as the affective process. In these affective processes, persuasion occurs without the comprehension of the message. Compared to the cognitive processes these affective processes do not change the underlying cognitive structure in order to change attitudes. Attitudes are formed or changed in a relatively automatic manner (Fazio, Sanbonmastu, Powell, and Kardes, 1986) bypassing the deliberate processing of cognitions.

Zajonc and colleagues (Zajonc, 1980; Zajonc and Markus, 1982) proposed the independence of the affective and cognitive processes in preference formation. They state that under certain conditions, like low consumer involvement, affective processes lead to preference formation in the absence of cognitive processes. In other studies (Moreland and Zajonc, 1979; Murhpy and Zajonc, 1993) they provide empirical support that mere exposure can lead to enhanced stimulus without cognitive processing of the stimulus. This theory of affect is based on the premise that there is no subjective control on the affective reactions elicited by the persuasive message.

Several models have described the two routes of attitude change. The Elaboration Likelihood Model (ELM) distinguishes between central and peripheral routes of attitude formation (Petty and Cacioppo, 1983). The central route emphasizes thoughtful information processing about the object. This is the cognitive route involving

comprehension and learning of the persuasive message and forming attitudinal judgments. The peripheral route characterizes attitude change without active thinking about the stimulus. This occurs under certain conditions, like low consumer involvement, when individuals devote less effort in evaluating the contents of the persuasive message. Attitudes are formed as a result of affective reactions generated by the executional elements of the stimulus.

Chaiken (1980) also proposed a similar dual processing model of attitude formation. She referred to the two processes as systematic and heuristic processing. Systematic processing changes the cognitive structure and is similar to the central route of the ELM. Heuristic processing occurs under low involvement and is slightly different that the peripheral route of ELM. In heuristic processing, there is no cognitive elaboration and attitudes are formed on the basis of simple decision rules. She suggests that individuals may agree with messages that contain more (vs. few) arguments, with experts (vs. non experts), with messages having consensus (Chaiken and Stangor, 1987). In other words, consumers encode length of message as its strength, consider experts as trustworthy and consensus as correct.

Classical conditioning (Staats and Staats, 1958) represents another mechanism of affective process of attitude change. Gorn (1992) provided evidence of this process in his experiment of effect of music on consumers' attitudes. The conditioned stimulus, pen, was paired with an unconditioned stimulus, music. He observed that respondents who were exposed to likeable music had more favorable attitudes towards the pen than respondents who were exposed to dislikeable music. Since music does not convey

cognitive information he concluded that the positive affect produced by music was transferred to the product via classical conditioning.

The process of attitudes formation towards 'drug requesting behavior' needs to be explored. Do attitudes towards 'drug requesting behavior' result due to changes in consumers underlying beliefs? Or are these attitudes formed as a result of the affective process? Or do both these processes have a joint role in attitude formation? Insights into these questions can help in identifying factors that need to be focused in order to create favorable attitudes towards drug requesting behavior.

2.3. Attitude towards the Ad

Understanding the effects of advertising on consumer behavior is important for developing and modifying communication strategies. Recent advertising research has paralleled the persuasion research of attitude formation from social psychology. Researchers have studied the formation of due to changes in the underlying brand beliefs (Lutz, 1975; Olsen and Mitchell, 1975). This is akin to the cognitive processes of persuasion.

Recently a number of studies have documented the affective consequences of attitude towards the ad (A_{ad}) in the formation of brand attitudes (A_b). This relationship is independent of the effect of ad on the underlying brand beliefs. The concept of A_{ad} was introduced by Shimp (1981), and Mitchell and Olson (1981). A_{ad} is defined as a '*predisposition to respond in a favorable or unfavorable manner to a particular advertising stimulus during a particular exposure occasion*' (Lutz, 1985). There is empirical evidence of a direct relationship between A_{ad} and brand attitudes A_b.

2.3.1. Cognitive and Affective Consequences of A_{ad}

Shimp (1981) discussed two mechanisms by which A_{ad} affects brand choice. According to Shimp cognitive and affective responses represent the two dimensions of A_{ad}. The cognitive mechanism takes place in high involvement situations. Persuasive messages in ads influence consumers' beliefs and evaluations of the brand. This creates an attitude towards the brand (A_b), and brand choice depends on the favorability of this A_b. He refers to the second mechanism as affect-referral and explains it with reference to classical conditioning. Affective responses, such as feelings of love, nostalgia or sorrow are generated without any conscious processing of the ad. Consumers transfer these affective responses to the brand to form brand attitudes, which in turn determines brand choice. This affective transfer occurs when consumers engage in minimal information processing.

Mitchell and Olson (1981) provided empirical support for the mediating effects of A_{ad}. Using a 4 X 4 Latin square design the authors manipulated repetition and ad content. Repetition was manipulated so that attitudes could be formed through mechanisms other than brand beliefs. Ad content was used to manipulate brand attribute beliefs. As expected brand attribute beliefs mediated attitude formation. They also observed the mediating role of A_{ad} on brand attitudes.

They posited the following mechanisms of the mediating role of A_{ad}. Using classical conditioning effect (similar to Shimp, 1981), they argued that the likeability of the ad is transferred without conscious processing to the brand. An alternative explanation according to the authors was that A_{ad} was not a separate construct. They interpreted that A_{ad} was a surrogate measure of salient but unmeasured brand beliefs and

that consumers consider A_{ad} as the evaluation of image-like cognitive representation of the brand in forming brand attitudes.

Lutz and colleagues (Lutz, 1985; Lutz, MacKenzie, and Belch, 1983) proposed four mechanisms of the mediating role of A_{ad} on A_b, and tested them empirically using structural equation modeling (Mackenzie, Lutz, and Belch, 1986). In their first mechanism known as the 'affect-transfer hypothesis' they posited that A_{ad} has a direct one-way causal flow from A_{ad} to A_b. The 'dual-mediation hypothesis' specifies an indirect flow of causation from A_{ad} to A_b through brand cognitions (C_b). The 'reciprocal-mediation hypothesis' portrays a reciprocal relationship between A_{ad} and A_b. The strength of reciprocal relationship varies across consumers and situations. In the 'independent-influence hypothesis' there is an independent effect of A_{ad} and A_b on purchase intentions, and assumes no causal relationship between A_{ad} and A_b.

The dual-mediation hypothesis was found to be relatively superior to the other three mechanisms. In the dual-mediation model, they found a strong relationship between A_{ad} and A_b, in low-involvement product class. This result concurs with prior research that A_{ad} is a potentially important mediator of persuasive messages in an ad and brand attitudes. A moderate relationship was observed between A_{ad} and brand cognitions. The presence of this relationship leads the authors to conclude the relative superiority of the dual-mediation model over the affect-transfer model. Homer (1990) replicated the study and found similar results. Thus A_{ad} influences the favorability of cognitive reactions to the brand as well as the overall brand attitude.

Brown and Stayman (1992) conducted a meta-analysis on the antecedents and consequences of attitude toward the A_{ad}. A pair-wise meta-analysis of 47 independent

samples from 43 different articles supported the robustness of the dual-mediation model. They observed two important results. First, they found a substantial and significant indirect path from A_{ad} to A_b via brand cognitions. Secondly, the relationship between A_{ad} and A_b was weaker than found in previous research. Based on these two findings they concluded that the indirect route was relatively more important than the direct route.

The attitude towards the ad research attempts to address the affective process of attitude formation and change. What is the role of attitudes towards DTC ad in drug requesting behavior? Are the persuasive messages in a DTC ad comprehended and evaluated to form attitudes towards drug requesting behavior? Or are the attitudes towards DTC ad transferred directly to attitudes towards requesting a drug without underlying cognitive changes? Does the dual-mediation model hold for DTC ads as well?

2.4. The Theory of Reasoned Action

In this section the main concepts of the theory of reasoned action are discussed and elaborated. The key assumptions underlying the theory are also examined. This is followed by limitations of the theory. Finally the applications and utility of the theory are evaluated. Research studies are mainly synthesized from the area of healthcare and marketing.

2.4.1. The Theory of Reasoned Action

An important issue among psychologists, marketing theorists and researchers is to understand and predict human behavior. The theory of reasoned action (TRA) examines how a person's behavioral intentions are the underlying factors in predicting his actual

behavior. The foundations of this theory can be traced to Dulany's theory of propositional control (Dulany, 1961; 1968), because Fishbein (1963; 1967) proposed his own model based on Dulany's theory and later extended it to the theory of reasoned action (Ajzen and Fishbein, 1980; Fishbein and Ajzen, 1975). The theory of reasoned action is a model of the psychological processes that fully mediate the relationship between attitudes and behavior.

The theory of reasoned action is based on the assumption that human beings are rational and have the ability to process and use the information available to them. Another assumption of the theory is that individuals have full volitional control of their behavior. That is individuals have willful control over their behavior and its intended outcomes.

The theory suggests that an individual's behavior is determined by his intentions to perform the behavior (figure 2). Behavioral intentions are defined as the individuals' subjective probability to perform the specific behavior. There are two conditions under which behavioral intentions can accurately predict actual behavior. First, intentions and behavioral measures should have a high degree of correspondence between them. Both intentions and behavioral measures need to be measured with a high degree of specificity with regard to the *action* being performed, the *target* at which the action is directed, the *context* in which the action occurs, and the *time* frame of performing the action. Secondly, intentions and behavior should not change in the interval between assessment of intentions and assessment of behavior.

According to the theory, behavioral intentions have two antecedents. They are determined by individual's a) attitude towards the behavior and their b) subjective norms

regarding the behavior. Attitude towards the behavior reflects an individual's positive or negative feelings associated with performing the behavior. According to Fishbein and Ajzen (1975), individuals will have favorable attitudes towards the behavior if they believe that performing the behavior will lead to mostly positive outcomes. On the other hand, if individuals believe that performing the behavior will result in mostly negative outcomes they will have a negative attitude towards the behavior.

The second antecedent of behavioral intentions reflects the social influence on the individual. It is the individual's perception about how significant others think about his / her performing the behavior. Subjective norm is a measure of the social pressure the individual faces to perform the behavior. Individuals will have a stronger subjective norm if they perceive important others expect them to perform the behavior. Subjective norm will be weak among individuals who perceive that important others expect them not to perform the behavior.

According to the theory, when individuals have favorable attitudes towards the behavior and when they believe important others think they should perform the behavior, they will usually intend to perform the behavior. The relative importance of these two factors determines the behavioral intentions. The theory assumes that the relative importance is determined by the intentions under investigation, and may vary across individuals. Thus by assessing individuals' attitude towards the behavior, their subjective norms and the relative importance of attitudes and subjective norms, the theory of reasoned action provides an understanding of individuals' intention to perform the behavior. The theory further explores the formation of attitudes and subjective norms.

Attitudes are made up of beliefs that individuals accumulate over their lifetime. These beliefs can be formed either from direct experience, outside information or may be self-generated through inference processes. However, only a few of these beliefs actually determine individuals' attitudes and are known as *accessible*[1] beliefs. To predict attitudes from beliefs the theory of reasoned action recommends four steps.

The first step is the elicitation of individual's accessible beliefs. Beliefs that are most frequently elicited, known as modal accessible beliefs, can be identified from a representative sample of the population. The second step is to measure how an individual evaluates the outcome (e_i) of each accessible belief by using a bipolar likert scale. The next step is to measure the belief strength (b_i). Belief strength is the likelihood that performing a behavior will result in a given outcome. Lastly, the product of each outcome evaluation multiplied by the corresponding belief strength is summed for total set of accessible beliefs. This outcome is used to predict an individual's attitude toward the behavior. The following equation describes the integration process.

$$A_{beh} = \Sigma\, b_i\, e_i$$

where A_{beh} = individual's attitude towards the behavior

b = belief strength

e = evaluation of the outcome

i = specific accessible belief (i=1 to n, where n = number of accessible beliefs)

Subjective norms are a function of normative beliefs. In determining subjective norms the theory states that salient referents need to be identified. In the context of actual

[1] In the original theory, these beliefs were known as *salient* beliefs (Fishbein, 1967; Fishbein and Ajzen, 1975). The authors (Ajzen and Fishbein, 2000), now refer to these beliefs as *accessible* beliefs based on the currently favored terminology (see Higgins, 1996).

studies, modal referents need to be created. The normative beliefs (NB_i) are measured using a bipolar likert scale. Then the individual's motivation to comply (MC_i) with each of the referent group is measured. Finally, the product of each normative belief multiplied by the individuals corresponding motivation to comply is summed. The outcome is used to predict the individual's subjective norm. This formulation is presented in the following equation.

$$SN = \Sigma\ NB_i\ MC_i$$

where SN = subjective norm

NB = normative beliefs

MC = motivation to comply

i = specific normative belief (i=1 to m, where m = number of normative beliefs)

In summary, according to the theory of reasoned action an individual's behavior is influenced by his behavioral intentions. These intentions are a function of the individual's attitude towards the behavior and his subjective norm. The individuals' attitude and subjective norm are both considered a function of their appropriate beliefs. This is represented symbolically as follows,

$$B \sim I = w_1\ (A_{beh}) + w_2\ (SN)$$

where B = behavior

I = behavioral intention

A_{beh} = attitude towards the behavior

SN = subjective norm

w_1, w_2 = relative importance of A_{beh} and SN

The theory of reasoned action is limited in its application to intentions and behavior. The theory was created to address behaviors and not the outcomes of those behaviors. The model also does not account for the failure to achieve the goal or the consequences of the failures. Further, behaviors that are not fully under volitional control are poorly predicted by the theory.

The theory of reasoned action has demonstrated its utility in numerous health-related and consumer behaviors. A review of the studies on the theory of reasoned action is presented in two broad categories. First, studies from the field of health care are synthesized that have addressed its predictive validity of the theory. Secondly, studies that have focused on the theory's conceptual and measurement issues are presented.

2.4.2. Research on health-related behavior using TRA

Testicular Self-Examination

The theory of reasoned action has been found useful in explaining testicular self-examination (TSE). Brubaker and Wickersham (1990) explored the impact of a field intervention on intentions to perform testicular self-exam among college students. Multiple regression results exhibited a significant correlation between intentions to perform TSE and attitudes and subjective norms. These two variables accounted for 39% of the variance in intentions. Attitudes predicted intentions better than subjective norms.

According to the theory the authors found significant correlations between beliefs and attitudes and between normative beliefs and subjective norms. They also found significant differences in behavior and normative beliefs between subjects who intended to perform TSE and those who did not intend to perform TSE. Since there was a long

follow up period of 6 weeks the correlation between intentions and behavior was moderate. This correlation was stronger among intenders of TSE and among those who were exposed to the message.

This study was extended further (Brubaker and Folwer, 1990) to evaluate the effects of a persuasive message based on the theory of reasoned action on the performance of TSE. In this study the authors used two persuasive messages. The experimental message contained statements to alter beliefs about the outcomes of performing TSE. The second message contained general information about testicular cancer. A third group, which served as a control group did not receive any message. The results provided partial evidence to the theory of reasoned action. According to the hypothesized model there was significant relationship between intentions and behavior. Further intentions mediated the effect of attitudes and subjective norms.

In addition, analyses of the persuasive messages revealed that the theory-based message produced stronger intentions to perform TSE as well higher TSE performance (self-reported) compared to the no-message group. However the authors noted no difference between the theory-based and information messages. Path analysis also revealed that the persuasive message had a direct influence on subjective norms, intentions and self-efficacy.

In another study Steffen (1990) also found empirical support for the theory of reasoned action to explain TSE. The author concluded that attitudes and subjective norms had a significant impact on intentions. In addition the group exposed to the persuasive message exhibited positive beliefs, attitudes and intentions. She also noted the effect of prior knowledge on intentions.

Breast Cancer

The theory of reasoned action has been helpful in understanding breast self-examination (BSE). Powell-Cope et al (Powell-Cope, Lierman, Kasprzyk, Young, and Benoliel1, 1991) reported two studies on the utility of the theory of reasoned action on BSE. In both studies only attitudes had a significant impact on BSE intentions. The attitudinal component had an impact on behavior only in the first study. In contrast behavior was only predicted by subjective norms in study 2. The authors attributed the varying degree of success of TRA on sample and design characteristics.

Lammers and Fox (1991) utilized the theory of reasoned action to predict and explain the performance of BSE. Using discriminant analysis they found that the theory was able to predict whether women performed BSE or not 94% of the time. Attitudinal factors accounted for a large proportion of variance than subjective norms. This result of the relative importance of attitudinal variable in BSE was also observed in other studies (Gardner and Rassaby, 1985; Horne, McDermott, and Gold, 1986; Lierman, Kasprzyk, and Benoliel, 1991).

In the area of breast cancer, mammography participation has also been studied using the theory of reasoned action. Montano et al (Montano and Taplin, 1991; Montano, Thompson, Taylor, and Mahloch, 1997) used an expanded theory of reasoned action to predict mammography intentions. They added affect, habit and facilitating conditions (Triandis, 1980) as additional predictors to the theory of reasoned action. The theory helped in explaining behavioral intentions and behavior in both the studies. As hypothesized the additional variables improved the theory's predictive ability. However there was an interesting difference in the two studies. In one study (1991) they used a

prospective design to predict the follow-up mammography behavior, and in the second study (1997) they used a retrospective design to explain prior mammography utilization. Higher correlations were obtained in the study with the prospective design, particularly in the prediction of behavior. Based on this finding Montano et al (1997) asserted that intentions and its antecedents are dynamic and change over time.

Organ Donation

The decision to donate bone marrow was investigated by Bagozzi et al (Bagozzi, Lee, and Van Loo, 2001) using the theory of reasoned action. In this study the authors modified the attitude component and represented it as a second order factor, which was indicated by two first-order affective and evaluative attitudinal factors. The theory was tested across four cultural groups using structural equation modeling. The results were consistent across all the groups and the theory helped in explaining moderate to high amount of variance in intentions to donate bone marrow. Formal tests of the measurement and structural parameters across the four cultural groups showed that most were of equal magnitude leading to evidence of generalizability of the theory of reasoned action.

The theory of reasoned action has been also used to study other organ donations. It has proved to be helpful in understanding kidney donation (Borgida, Conner and Manteufel, 1992) and blood donation (Bagozzi, 1981a, 1986, 1989; Burnkrant and Page, 1988).

Treatment Compliance

The theory of reasoned action has provided insights into patients' treatment compliance. Reid et al (Reid, Oleen, Martinson and Pluhar, 1985) explained the intentions to comply with antihypertensive regimens by male patients using the theory of reasoned action and the health belief model. Their path analysis results indicated that attitudes and subjective norms had the greatest direct impact on intentions to comply with the treatment. Reid et al also noted an indirect effect of physicians' normative expectations on patients' attitudes. In fact physicians expectations had the largest total effect (direct + indirect) on intentions. Perceived susceptibility of the disease was an additional variable that significantly predicted intentions. Overall, the model explained 35% of the variance in compliance intentions.

Reid and Christensen (1988) replicated the study to explain treatment compliance behavior among female patients with uncomplicated urinary tract infections. Three TRA variables: belief strength, outcome evaluations, and behavioral intentions significantly predicted compliance. The social variables did not contribute in explaining compliance. However, they were the strongest predictors of compliance intentions. The authors argued that for acute diseases, significant others only influence intentions and do not carry over to actual behavior, but for chronic diseases social influences could be important to ensure compliance. TRA variables explained an additional 19% of the variance over the health belief model variables.

The usefulness of the theory of reasoned action in explaining the intention to use non-prescription analgesics was demonstrated by Chinburapa and Larson (1990). About 87% of variance in intentions was explained by attitudes and social norms. Attitudes had

a larger impact on intentions than subjective norms. The authors conceptualized attitudes into cognitive and affective components. They observed that cognitive attitudes, subjective norms and past behavior influenced intentions indirectly through affective attitudes in contrast to the theory of reasoned action.

Other Health-related Behaviors

There are numerous behaviors in the field of health-care that have been studied using the theory of reasoned action. A summary of theory's usefulness in HIV-preventive behavior is documented by Abraham et al (Abraham, Sheeran, and Orbell, 1998) and in the meta-analysis conducted by Albarracin et al (Albarracín, Johnson, Fishbein, and Muellerleile, 2001). Support for the theory's predictive ability in exercise behavior and physical activity can be found in the meta-analysis conducted by Hausenblas et al and Hagger et al respectively (Hagger, Chatzisarantis, and Biddle, 2002; Hausenblas, Carron, and Mack,1997). The theory has also been applied to investigate physicians behavior to prescribe antibiotics (Lambert, Salmon, Stubbings, Gilomen-Study, Valuck, and Kezlarian,1997), to deliver preventive services (Millstein, 1996), and to use drug information sources (Gaither, Bagozzi, Ascione, and Kirking, 1997).

2.4.3. Research on Conceptual and Measurement Issues

Researchers have also addressed and investigated the conceptual and measurement issues of the theory of reasoned action. Some researchers have considered different ways of defining and measuring the theoretical constructs. While others have

suggested modifications in the inter-relationships amongst the model components. This section attempts to summarize these issues.

Multidimensionality of Constructs

The unidimensional nature of the attitudinal component was questioned by Bagozzi (1981a). When he operationalized attitudes with a semantic differential scale, they were found to exist as a unidimensional construct. However when he used expectancy-value modeling, he observed that attitudes were multi-dimensional in nature.

Shimp and Kavas (1984) represented the cognitive and normative structures as multidimensional factors. When the cognitive structure was represented by three separate expectancy-value factors, the model explained nearly 59 percent variance of attitude towards coupon usage, compared to less than 2 percent with a unidimensional representation. They argued that cognitive elements about the consequences of a behavior could differ qualitatively and need not be organized into a singular cognitive unit. A similar operationalization of the normative structure revealed that 'spouse' was a strong determinant of subjective norms regarding the behavior.

In a recent study, Bagozzi et al (2001) operationalized attitude as a higher second order factor composed of affective and evaluative attitudinal components. They used semantic differential scale and found strong support to the existence and functionality of the multidimensional representation. A similar result was obtained by Ajzen and Driver (1991). A factor analysis of their semantic differential items also revealed an evaluative and an affective attitudinal factor similar to that found by Bagozzi et al.

Evidence on the multidimensionality of the normative component was documented by Burnkrant and Page (1988). The normative component comprised of socially mediated rewards and punishments. Also subjective norm to donate blood was represented as a two dimensional construct; spouse & friends and parents & employer. Besides evidence of convergent and discriminant validity these two dimensions of subjective norms differed in their ability to predict intentions.

Interdependency and Crossover Effects

According to the theory of reasoned action, attitudes and subjective norms are distinct and independent components. Miniard and Cohen (1979; 1981) argued that due to operational definitions, attitudes and subjective norms cannot be completely isolated from each other. In their study they manipulated normative and attitudinal influence on respondents. They reported that manipulation of normative influence had an effect on attitudinal as well as normative measures. Similarly, manipulations of attitudes had an effect on both sets of measures.

Ryan (1982) studied the interdependency of the attitudinal and normative components and inferred that though these two variables exhibited different mediating effects on intentions they were not independent of each other. Further, Burnkrant and Page (1982) examined the convergent and discriminant validity of these two components. They found evidence of both convergent and discriminant validity. They also noted a significant correlation between the two components and reasoned that the social component could lead individuals to use referents as sources of both attitudinal and normative influence.

Shimp and Kavas (1984) provided empirical evidence of the crossover influence of belief structures on attitudes and subjective norms. They observed improvement in model fit when crossover effects were added to the theory of reasoned action to explain coupon usage. The crossover effect between normative beliefs and attitudes was stronger than the crossover effect between cognitive beliefs and subjective norms. They inferred, according to the theory, that the normative belief to attitude linkage was due to the consequences of behavior on significant others. While the cognitive belief and subjective norm link was due to the false consensus notion (Ross, 1977) where strongly held beliefs are imagined to be held by others.

Studying the intentions to use non-prescription analgesics, Chinburapa and Larson (1990) observed an effect between subjective norms and behavioral intentions that was mediated by affective attitudes. A similar result was observed by Reid et al (Reid, Oleen, Martinson, and Pluhar, 1985) in their study on compliance of hypertensive regimens. They noted a direct effect of physicians' normative expectations on patients' attitude towards compliance.

Process of Attitude Formation

Fishbein and Misdlestadt (1995, 1997) maintain the centrality of the belief-based processes (i.e. cognitive processes) in attitude formation. According to them when cognitive structure is operationalized according to the theory of reasoned action, it will mediate all the effect of affect generated by the persuasive message on attitudes. They argue that evidence in favor of affective processes of attitude formation and change is

limited due to inadequate assessment of the cognitive structure. They attribute the direct effect of affect on attitudes to methodological artifacts.

This conclusion was challenged by various authors in a series of replies (Haugtvet et al, 1997; Herr, 1995; Miniard and Barone, 1997; Priester and Fleming, 1997; Schwarz, 1997). They argue against the singular belief-based process of attitude formation and change. Miniard and Barone (1997) present evidence from the persuasion literature supporting non-belief based processes of attitude formation.

Priester and Fleming (1997) present three arguments in response to Fishbein and Middlestad (1995). They present evidence of a number of processes that influence attitudes, which can be conceptualized as non-belief based processes. Next, they highlight studies where attitude formation resulted from non-belief and belief-based processes when they were assessed by same measures of attitudes and beliefs. And lastly, they state that different attitude change processes, lead to attitudes that were consistent, predictable and had meaningful differences.

Haugtvedt et al (1997) reviewed the role of moderator variables that influence the attitude formation and change processes. Using examples of attitude theories that allow for multiple processes, they present evidence of consistency of the moderation processes. They note that this moderation is relatively weak in theories that emphasize a singular process of attitude formation.

2.4.4. TRA and Drug Requesting Behavior

The validity of the theory of reasoned action has been supported by numerous behavioral studies. The theory has shown remarkable generalizability across various

behaviors. Against a backdrop of the relevance to predict and explain various health related behaviors, it is expected that the theory would provide explanation to various antecedents of drug requesting behavior. What is the differential impact of attitudes and subjective norms on intentions to request a drug from a physician? What impact do behavioral and normative beliefs have on these two antecedents? In an attempt to fully understand 'drug requesting behavior', it is expected that the theory would help in explaining the underlying processes leading to intentions to perform the behavior.

2.5. Past Behavior / Habit and Trust

The theory of reasoned action is a parsimonious attitudinal model that explains determinants of behavior. By assessing individuals' perceived behavioral control this theory has been extended to the theory of planned behavior that explains non-volitional behaviors. Researchers have also added other variables such as self-identity, habit, self-efficiency, etc., to the theory of reasoned action in order to increase its predictive ability. This section focuses on two constructs past behavior or habit and trust in physicians as candidate variables that can help in supplementing the theory's explanatory power in understanding patients' drug requesting behavior.

2.5.1 Past Behavior or Habit

According to the theory of reasoned action, attitudes and subjective norms fully predict intentions. The influence of all other variables on intentions is supposed to be mediated via attitudes and subjective norms. Similarly since intentions predict behavior, all other variables should have an indirect effect on behavior via intentions. However,

there is evidence that past behavior has a direct effect on intentions as well as on future behavior.

Bentler and Speckart (1979) were the first to study the effect of past behavior in the context of reasoned actions. They argued that if attitudes are partially self-generated inferences from past behavior, then past behavior should have an independent role in the prediction of future behavior. They extended this argument to predict intentions. They proposed that intentions could also be partially generated by perceptions of past behavior, reflecting a presence of a direct relationship between them. Using structural equation modeling they found empirical evidence of a direct effect of past behavior on both intentions and future behavior. Similar results were obtained by Bagozzi (1981b) and Fredricks and Dossett (1993).

There are various explanations offered by researchers that account for the direct effect of past behavior on intentions and future behavior. Ajzen (1991) attributed the residual effects of past behavior obtained in many studies to shared method variance in the measurement of past and future behavior. Another methodological rationale offered by Bagozzi and Kimmer (1995) is that past behavior serves as a covariate or control in the statistical analysis.

A theoretical explanation for the association between past and later behavior is also documented (Ronis, Yates and Kirscht, 1989; Triandis, 1980). According to this view, behavior is dependent on a learning process. Infrequent or new behaviors are usually under volitional control of the individual. In case of behaviors that are repeated, outcomes of past behavior are encoded in memory and are retrieved when the individual encounters familiar environmental cues leading to cognitive efficiency. These effects of

outcomes of past behavior serve as input to form intentions or to perform future behavior. When a particular behavior is performed repeatedly, these non-volitional processes are expected to guide behavior automatically and are referred to as habit.

Bagozzi (1981b), operationalized past behavior as frequency of blood donation in the last five years. When past behavior was included as an explanatory variable to study future blood donation behavior, the attitude-intention relationship was attenuated, implying an independent effect of past behavior on intentions. Also past behavior decreased the impact of intentions on behavior, further suggesting its direct effect on behavior.

In the domain of breast cancer behaviors, Orbell, Hodgkins and Sheeran (1997) found that previous breast self-examination behavior had a significant effect on future behavior. They however found that intentions attenuate the link between past and future behavior. They concluded that implementation intentions mimic the effect of habit in breast self-examination. Baumann, Brown, Fontana and Cameron (1993) observed a strong correlation between habit and intention to obtain mammography in the next two years. They operationalized habit as number of mammograms received over the past three years.

Examining the intention to use non-prescription analgesics Chinburapa and Larson (1991) found support to the theory of reasoned action. They observed only an indirect effect of past behavior on intentions. This effect was mediated by affective attitudes. They concluded that affective attitudes are not fully formed through information processing, but may also be partially formed by the outcomes of past behavior.

In the context of drug requesting behavior, how does past behavior play a role in intentions to request a drug from a physician? Does past behavior help in predicting the variance in drug requesting behavior beyond the variables of the theory of reasoned action? Or is the impact of past behavior fully mediated by attitudes?

2.5.2. Trust in Physician

Trust has been identified as a critical element in the patient-physician relationship (Hillman, 1998). A number of studies have documented the relationship between trust and effective medical care (Kao, Green, Zaslavsky, Koplan, and Cleary, 1998; Safran, Taira, Rogers, Kosinski, Ware, and Tarlov 1998; Thom, Ribisl, Stewart, Luke, and The Stanford Trust Study Physicians, 1999). In this section a summary of studies that have explored the role of trust on patient-physician relationship and health outcomes is presented. Some theories are drawn from the field of marketing to emphasize its importance in the dyad relationship.

Trust in physician is defined as '*the patients expectation that the physicians will perform their responsibilities in a technically proficient way, that physicians will assume responsibility and not inappropriately defer to others, and that physicians will make patients' welfare their highest priority*' (Mechanic and Schlesinger, 1996). Thom et al (Thom and the Stanford Trust Study Physicians, 2001) studied the antecedents of trust under the domain of physicians' behavior. They found caring and comforting attitude, technical competence, and good communication skills of the physician were important predictors of patients' trust in their physician.

Safran et al (Safran, Taira, Rogers, Kosinski, Ware, and Tarlov 1998) examined the role of primary care performance on health outcomes. Using the Primary Care Assessment Survey (PCAS), which has a trust subscale, they assessed the relationship between trust and three health outcomes; self-reported adherence to treatment, patient satisfaction in physician, and improved health status. They found trust was a significant predictor of adherence to treatment and patient satisfaction. Patients having trust scores in the 95th percentile reported a 43.1% adherence compared to 17.5% adherence by patients who had trust scores in the 5th percentile. Patients with 95th percentile trust score were about 5 times more likely to express complete satisfaction than those with median level of trust.

Thom et al (Thom, Ribisl, Stewart, Luke, and the Stanford Trust Study Physicians, 1999) also used trust as a predictor of self-reported adherence to prescribed medication, satisfaction with care from the physician, and continuation with the same physician after 6 months. They measured trust using the Trust in Physician Scale (TPS; Anderson and Dedrick, 1990) and controlled for demographic and baseline variables like length of relationship, choice of physician, patient preference for autonomy and self-care. Using MANOVA, and after adjustment of the covariates they found trust to be a significant predictor of patients' satisfaction, adherence to treatment and continuity with the same physician assessed after 6 months.

Kravitz and colleagues (Kravitz, Bell, Azari, Krupal, Kelly-Reif, and Thom, 2002) studied the antecedents and consequences of patients' request fulfillment on health outcomes. Various types of patient requests were measured, including request for a new medication from a physician. Using multiple regression analysis the authors found that

previsit trust in physician was an important predictor of request fulfillment and satisfaction. They argued that patients who trust their physicians are less likely to make bothersome requests and exhibit cordial behavior so that physicians grant their request.

The importance of trust in a relationship between two entities has been expressed in the marketing discipline. The Commitment-Trust Theory (Morgan and Hunt, 1994) states that commitment and trust are mediators of successful relationship marketing. Building on the commitment-trust theory, Garbarino and Johnson (1999) have demonstrated that for high relational customers, trust and commitment are key mediators between attitudes and future intentions. A meta-analysis of the antecedents and consequences of trust in a sales context points out that trust has a moderate but beneficial influence on the development of positive customer attitudes, intentions, and behavior (Swan, Bowers, and Richardson, 1999). It has been noted that trust enhances the likelihood of future interactions among parties (Doney and Cannon, 1997).

The review of the trust literature emphasizes the central role of trust in successful relationships. In the domain of patient-physician relationship what role does trust play in exhibiting drug requesting behavior? Is trust an important antecedent in the formation of intentions to request a drug from a physician? Does it have an effect that is independent of the subjective norm (of the physician) component of the theory of the reasoned action? Or does it have an indirect effect on intention formation? Insights into these research questions can help to understand the relative importance of trust in drug requests in comparison to the components of the theory of reasoned action.

CHAPTER 3

RESEARCH QUESTIONS AND HYPOTHESES

This research study will examine the determinants of patients' intention to request a drug from their physician. It is believed that predicting and understanding the antecedents of patients' drug requesting behavior can provide useful insights in influencing this behavior. Specifying the factors and the psychological processes that influence patients' intentions to request a drug can be helpful in predicting their behavior.

3.1. Research Questions and Rationale

Specifically, this research will study patients' drug requesting behavior in three phases. In phase one, the effect of direct-to-consumer (DTC) advertising on this behavior is explored. Substantial research suggests a positive relationship between awareness of DTC ads and interactions with a health care professional. It is also observed that consumers search for more information as a result of DTC ads. However, a small amount of research has examined the process by which DTC ads affect consumers' behavior.

The first objective of this research is to address the persuasive mechanism of DTC ads. It is important to understand the psychological processes that mediate the changes in the consumer's attitude towards drug requesting behavior on exposure to a DTC ad. What is the role of attitudes towards DTC ads in patients' drug requesting behavior? Do attitudes towards drug requesting behavior result due to changes in consumers' underlying beliefs? Or are the attitudes towards DTC ads transferred directly to attitudes

towards requesting a drug as a result of the affective processes? A conceptual framework of the consequences of attitudes towards the DTC ads is presented in figure 3.

In the second phase, the theory of reasoned action will be used to study the antecedents of drug requesting behavior. This theory has been used to study numerous health related behaviors. Studying this behavior under this theoretical framework will provide domains for identifying drug requestors and non-requestors. The present study seeks evidence to empirically validate the theory of reasoned action in explaining consumers' drug requesting behavior.

The theory of reasoned action assumes that intentions are good predictors of overt behavior. Intentions in turn have two antecedents. They are determined by individual's attitude towards drug requesting behavior and their subjective norm regarding the behavior. Attitudes and subjective norms are formed as a result of behavioral and normative beliefs respectively. Does the theory of reasoned action help in explaining patients' intentions to request a drug from their physician? What is the differential impact of attitudes and subjective norms on intentions? Does attitudes and subjective norm mediate the impact of behavioral and normative beliefs? Or is there a presence of a cross over effect among the model components? Figure 4 outlines the portion of the theory of reasoned action that will be tested to predict patients' intentions to request a drug.

In the final phase, the research considers two more important antecedents; past behavior or habit and trust in physician. The aim of this section is not to replace the theory of reasoned action, but to build on it and supplement its power to predict drug-requesting behavior. This final stage integrates the theory of reasoned action, past

behavior and trust, with the aim of developing a comprehensive model in examining patients' intentions of requesting a drug from a physician (figure 5).

The concept of habit states that behavior can occur due to activation of automatic psychological processes as a result of past behavior, rather than deliberate to perform the behavior every time (Ronis, Yates, and Kirscht, 1989). One limitation of the theory of reasoned action is that it does not account for the impact of past behavior on intentions. This research attempts to model the role of past behavior as a relevant antecedent of patients' drug requesting behavior. How does patients' past behavior impact their intentions to request a drug from their physician? Does past behavior improve the prediction of intentions beyond the theory of reasoned action? Or is the impact of past behavior mediated by attitudes?

Trust is considered to be an important aspect in the patient-physician relationship. Even when patients are well informed about health care, they still have to depend on their physician for a prescription. The element of trust seems to be crucial in patients' intention to request a drug from their physician.

This study seeks to assess the impact and direction of trust on patients' drug requesting behavior. It can be conjectured that trust in a physician could result in accepting the physician's choice of a prescription drug. On the other hand, it is also plausible that higher level of trust can trigger a drug request, in order to gain justification of its suitability from the physician. Hence examining the direction is useful in analyzing the relationship. Does trust in physician have a direct impact on formation of intentions to request a drug? Or does it have an indirect effect via the subjective norm component of the theory of reasoned action?

3.2. Research Hypotheses

3.2.1. Cognitive and Affective Consequences of Attitude towards DTC ads

The first section of the research investigates the consequences of consumers' attitudes towards DTC ads. It explores the persuasive mechanism of consumers' attitude formation and change after they are exposed to a DTC ad.

According to the belief-based models (Fishbein and Ajzen, 1975) consumers' attitudes are determined by their beliefs. Attitude refers to consumer's favorable or unfavorable evaluation of an object. The object could be a person, issue, event, behavior etc. Beliefs refer to the information the consumer has about the object. Beliefs denote the overall knowledge, opinion, and thoughts the consumer has about the object. Specifically, consumers' will form beliefs about requesting the advertised drug. These beliefs will influence the consumers' attitude towards their behavior. Their attitudes are related to the beliefs that performing the behavior will lead to certain consequences (i.e. belief strength) ant their evaluation of those consequences. The assessment of belief strength and evaluation of the consequences is known as the cognitive structure.

These belief-based models advocate that the consumers' cognitive structure determines their attitudes. It emphasizes that the cognitive structure mediates the influence of all persuasive messages on consumers' attitudes. This implies that the persuasive message in DTC ads changes consumers underlying cognitive structure, that is, their beliefs about drug requesting behavior. As a result of this change in the cognitive structure consumers' attitudes towards requesting a drug are changed. This cognitive process of attitude formation suggests the following two hypotheses.

H1: Consumers' attitude towards DTC ads will significantly influence their beliefs about requesting the advertised drug from their physician.

H2: Consumers' beliefs about requesting the advertised drug from their physician will significantly influence their attitude towards drug requesting behavior.

In the affective process of attitude formation, attitudes are formed without any change in the underlying cognitive structure. There are several theories that support this non-belief based process of persuasion. Zajonc and colleagues (Zajonc, 1980; Zajonc and Markus, 1982) argued that the affective process is independent of the cognitive process and may precede cognitive information processing. They suggested that under certain conditions, like low consumer involvement, attitudes could be formed without influencing consumers' beliefs.

Another explanation to the affective process of affective process of persuasion is the classical conditioning mechanism (Staats and Staats, 1958). The classical conditioning perspective suggests that positive attitudes towards a behavior (conditioned stimulus) may be developed through its association with other stimuli (unconditioned stimuli) in the persuasive message, which are also evaluated positively. Examples of unconditioned stimuli are attractive colors, music, fear, etc.

The Elaboration Likelihood Model (ELM) distinguishes between the two routes of persuasion (Petty and Cacioppo, 1983). The central route emphasizes the cognitive information consumers have regarding the issue under consideration. In contrast, the peripheral route characterizes attitude change without active thinking about the attributes of the issue. The peripheral route of persuasion occurs when the level of involvement of the consumer is low.

Chaiken (1980) also differentiated the two routes of persuasion. The systemic processing is similar to the central processing of the ELM. In heuristic processing, which

occurs under low involvement condition, attitudes are formed via simple decision rules, such as, length of message implies strength, experts statements are trustworthy, etc. In heuristic processing consumers exert comparatively little effort in processing the information content in the message.

Shimp (1981) and Mitchell and Olson (1981) proposed that attitude towards the ad has an independent influence on brand attitudes without affecting consumers' brand beliefs. The affective responses, such as feelings of joy, nostalgia, fear, etc. that are generated without conscious processing of the ad are transferred directly to the brand to form brand attitudes. This affective transfer occurs when consumers engage in minimal information processing. Thus the affective process of attitude formation leads to the following hypothesis.

H3: Consumers' attitude towards DTC ads will significantly influence their attitude towards drug requesting behavior.

Consumers' involvement also plays a major role in information processing. Involvement can be defined as *'a person's perceived relevance of the object based on inherent needs, values, and interests'* (Zaichkowsky, 1985). Research has shown that consumers' involvement has a considerable impact on how attitudes are formed or changed (Chaiken, 1980; Petty and Cacioppo, 1981)

These studies indicate that consumers' who are highly involved with an issue are likely to process the persuasive message in detail. As involvement increases consumers devote cognitive effort to evaluate the message content and attempt to ascertain the validity of the arguments in the message. On the other hand if consumers are in a 'low-involvement state' they are less likely to engage in message-related thinking. In such

situations, the peripheral aspects of the messages, such as, source characteristics, creative features, celebrity endorsement, background, etc. influences attitude formation or change. Thus the issue of involvement in information processing leads to the next hypothesis.

H4: Attitude towards DTC ads will have a significantly lower level of direct influence on attitude towards drug requesting behavior among consumers who are more involved in the medical condition.

The belief-based models state that consumers form behavioral intentions on the basis of their attitudes. Consumers with favorable attitudes would intend to perform the behavior, whereas consumers with unfavorable attitudes may not intend to perform the behavior (Fishbein and Ajzen, 1975). Thus consumers' intention to request the advertised drug from their physician depends on their attitudes towards requesting the drug during their next visit with the physician.

Gorn's (1982) study on the impact of music in an ad on brand choice represents a direct relationship between attitude towards the ad and purchase intentions. Subjects who had favorable evaluations of the music indicated choice behavior, but could not provide any cognitive reasoning for their choice. Thus it is possible for consumers to form behavioral intentions without actually undergoing cognitive change or forming favorable attitudes towards drug requesting behavior. A favorable attitude towards the ad can have a direct impact on behavioral intentions. However this effect is conjectured to be weak in comparison to the belief-based models. This can be hypothesized as follows.

H5: Consumers' intention to request the advertised drug from their physician will be influenced more by their attitude towards drug requesting behavior than by their attitude towards DTC ads.

An alternative approach to study the role of attitudes is to conceive attitude as multidimensional in nature. Breckler and Wiggins (1989) referred to the two dimensions of attitudes as 'evaluative' and 'affective'. The evaluative dimension can be defined as '*the imputation of some degree of goodness or badness to an entity*' (Eagly and Chaiken, 1993). It refers to consumers' judgment about the attitude object. The affective component refers to '*feelings, moods, emotion, and sympathetic nervous system activity that people experience in relation to attitude objects'* (Eagly and Chaiken, 1993).

Results from the Breckler and Wiggins (1989) study support the distinction between the evaluative and the affective component. A limitation of their study is that individual items were combined according to aprori specification and no factor analyses were conducted to verify the multidimensionality.

Shimp (1981) also proposed that attitude towards the ad may consist of a cognitive (i.e. evaluative) and an emotional (i.e. affective) dimension. According to him, the evaluative dimension represents the conscious processing of informational elements in the ad. Whereas the affective dimension comprises of consumers' emotional responses to the ad and are formed without conscious processing.

Miniard, Bhatla, and Rose (1990) decomposed attitude towards the ad into claim and non-claim elements. The claim-related element represents evaluation based on the perceived strength of the claims made in an ad's copy, and the non-claim element represents the evaluation of the non-claim elements in the copy. Using confirmatory factor analyses they provided evidence of the discriminant validity between these two components.

In a recent study, Bagozzi et al (2001) operationalized attitude as a higher second order factor composed of affective and evaluative attitudinal components. They used semantic differential scale and found strong support to the existence and functionality of the multidimensional representation. A similar result was obtained by Ajzen and Driver (1991). A factor analysis of their semantic differential items also revealed an evaluative and an affective attitudinal factor similar to that found by Bagozzi et al.

In the context of the present study, it is expected that attitude towards DTC ads are composed of evaluative and affective components. When consumers process information presented in a DTC ad they could form attitudes that are evaluative in nature. Alternatively attitudes can also be formed due to non-conscious processing as a result of feelings of joy, expectations, happiness, etc as a result of the ad. This would constitute the affective component of attitude towards the DTC ad.

Similarly, consumers' attitude towards requesting a drug from their physician is believed to have evaluative and affective dimensions. Evaluative attitudes could be formed as a result of conscious processing, whereas the affective attitudes could result due to feelings of eagerness, inquisitiveness, or satisfaction, etc that consumers anticipate if they request the advertised drug from their physician. In view of the multidimensional nature of attitudes the following hypotheses are derived.

H6: Consumers' attitude towards DTC ads is composed of evaluative and affective components.

H7: Consumers' attitude towards drug requesting behavior is composed of evaluative and affective components.

After providing empirical evidence of the distinctiveness of the evaluative and affective dimensions of attitude, Breckler and Wiggins (1989) expressed that future

research should establish the distinct roles played by affect versus evaluation in the structure of attitudes. Affect and evaluation could be associated with unique process and mechanisms of attitude formation and change. Persuasive messages may be more effective in changing evaluations, whereas classical conditioning procedures may be useful to modify affective attitudes (Batra and Ray, 1985).

Zajonc and colleagues (Zajonc, 1980; Zajonc and Markus, 1982) argued that the affective process is independent of the cognitive process and may precede cognitive information processing. They state that under certain conditions cognitive component may be dominant, and in other cases affective factors may be primary and dominant.

Edwards (1990) found that affect-based attitudes exhibited more change under affective means of persuasion than under cognitive means of persuasion. The affective reactions exert a primary influence on the consumer and attitude is initially formed with minimal cognitive appraisal. Cognition-based attitudes (i.e. evaluative) on the other hand exhibited equal change under both forms of persuasion. In this case, domain-relevant information is acquired first and affective factors come into play only after, and as a result of, considerable cognitive appraisal.

Thus consumers' evaluative attitude towards DTC ads is expected to influence their cognitive structure (i.e. beliefs) about requesting the advertised drug from their physician. Further using the classical conditioning mechanism it is anticipated that consumers' affective attitude towards DTC ads will be transferred to create affective attitudes towards drug requesting behavior. In an attempt to understand the multidimensionality of attitudes hypotheses H1 and H3 are further investigated as follows.

H8: Consumers' evaluative attitude towards a DTC ad will significantly influence their beliefs about requesting the advertised drug from their physician.

H9: Consumers' affective attitude towards a DTC ad will significantly influence their affective attitude towards drug-requesting behavior.

3.2.2. The Theory of Reasoned Action

The second section of the research focuses on the application of the theory of reasoned action to predict consumers' intention to request the advertised drug from their physician. Variations of the theoretical model are also investigated.

According to the theory, behavioral intentions have two antecedents. They are determined by individual's attitude towards the behavior and their subjective norms regarding the behavior. Attitude towards the behavior reflects an individual's positive or negative feelings associated with performing the behavior. According to Fishbein and Ajzen (1975), individuals will have favorable attitudes towards the behavior if they believe that performing the behavior will lead to mostly positive outcomes. On the other hand, if individuals believe that performing the behavior will result in mostly negative outcomes they will have a negative attitude towards the behavior.

The second antecedent of behavioral intentions reflects the social influence on the individual. It is the individual's perception about how significant others think about his / her performing the behavior. Subjective norm is a measure of the social pressure the individual faces to perform the behavior. Individuals will have a stronger subjective norm if they perceive important others expect them to perform the behavior. Subjective norm will be weak among individuals who perceive that important others expect them not to perform the behavior. This is tested in the next hypothesis.

H10: Consumers' attitudes and subjective norms about drug requesting behavior will significantly influence their intentions to request the advertised drug from their physician.

The theory of reasoned action states that consumers' attitudes are determined by their beliefs. This issue has been addressed in the previous section and the hypothesis is restated again for convenience.

H2: Consumers' beliefs about requesting the advertised drug from their physician will significantly influence their attitude towards drug requesting behavior.

Subjective norms are a function of normative beliefs. These normative beliefs refer to consumers' opinions that certain referents think he or she should or should not perform the behavior to request the advertised drug from their physician. The consumer may or may not be motivated with the referents. These normative beliefs and motivation to comply is termed as normative structure that leads to the formation of subjective norms. This relationship is rested in the following hypothesis.

H11: Consumers' normative beliefs about requesting the advertised drug will significantly influence their subjective norms about drug requesting behavior.

The theory of reasoned action assumes that the attitudinal and subjective norm components are independent of each other. In contrast, research has shown that the model components are interdependent (Miniard and Cohen, 1979, 1981; Oliver and Bearden, 1985; Ryan, 1982; Shimp and Kavas, 1984).

Shimp and Kavas (1984) attributed the crossover effect from cognitive structure to subjective norm to the notion of '*false consensus*' (Ross, 1977; Ross, Greene, and House, 1977). The notion of '*false consensus*' states that certain individuals believe that most people are similar. This leads them to believe that their own behavioral choices and

judgments are common and appropriate and attribute this as the social norm. Applied to drug requesting behavior, it is expected that consumers' personal beliefs would lead them to infer thoughts and opinions of their referents groups about requesting the advertised from a physician. This is stated in the next hypothesis.

H12: Consumers' beliefs about requesting the advertised drug will significantly influence their subjective norms about drug requesting behavior.

The second crossover effect from normative structure to attitudes represents the impact of social influence directly on consumers' attitudes (Kelman, 1961; Smith, 1984). The issue of social influence recognizes the readiness or vulnerability of consumers to integrate social beliefs during attitude formation. It is reasoned that consumers are motivated to comply with social beliefs to gain rewards or meet the expectations of significant others. This process of internalization of social beliefs depicts the crossover effect from normative structure to attitude and is stated in the next hypothesis.

H13: Consumers' normative beliefs about requesting the advertised drug will significantly influence their attitudes towards drug requesting behavior.

It is also argued that belief interdependencies result in a reciprocal relationship between attitudes and subjective norms (Ryan, 1982; Shimp and Kavas, 1984). Ryan stated that once attitudes and subjective norms are formed from beliefs, internalized predisposition (attitudes) could be related to an external expectation (subjective norm) and vice versa. Shimp and Kavas (1984) suggested that since attitudes and subjective norms represent cognitive outcomes that are logically coupled in memory, they could directly influence each other. This is stated in the next hypothesis as follows.

H14: Consumers' attitudes and subjective norms about drug requesting behavior will have a significant effect on each other.

3.2.3. Role of Past Behavior and Trust in Physician

The final section of the research studies the role of past behavior and trust in physician in explaining consumers' intention to request the advertised drug from their physician. It is believed that past behavior and trust will increase the predictive ability of the theory of reasoned action.

Bentler and Speckart (1979) were the first to study the effect of past behavior in the context of reasoned actions. They argued that if attitudes are partially self-generated inferences from past behavior, then past behavior should have an independent role in the prediction of future behavior. They extended this argument to predict intentions. They proposed that intentions could also be partially generated by perceptions of past behavior, reflecting a presence of a direct relationship between them.

A theoretical explanation for the association between past and later behavior is also documented (Ronis, Yates and Kirscht, 1989; Triandis, 1980). According to this view, behavior is dependent on a learning process. Infrequent or new behaviors are usually under volitional control of the individual. In case of behaviors that are repeated, outcomes of past behavior are encoded in memory and are retrieved when the individual encounters familiar environmental cues. These effects of outcomes of past behavior serve as input to form intentions or to perform future behavior as a result of cognitive efficiency. When a particular behavior is performed repeatedly, these non-volitional processes are expected to guide behavior automatically and are referred to as habit.

It is believed that some consumers interact with their physicians more than others. Some consumers are more curious about the medical condition, its impact on their life-style, the diagnostic procedures, the various treatment options, etc. It is expected that

consumers who exhibit a habitual behavior of asking their physicians questions pertaining to their medical condition will be more likely to request the advertised drug from their physician. The next hypothesis tests the relationship between past behavior and intentions.

H15: Consumers' past requesting behavior will significantly influence their intentions to request the advertised drug.

Trust has been identified as a critical element in the patient-physician relationship (Hillman, 1998). Thom et al (Thom and the Stanford Trust Study Physicians, 2001) studied the antecedents of trust under the domain of physicians' behavior. They found caring and comforting attitude, technical competence, and good communication skills of the physician were important predictors of patients' trust in their physician. Safran et al (Safran, Taira, Rogers, Kosinski, Ware, and Tarlov 1998) found that trust was a significant predictor of adherence to treatment and patient satisfaction.

Kravitz and colleagues (Kravitz, Bell, Azari, Krupal, Kelly-Reif, and Thom, 2002) studied the antecedents and consequences of patients' request fulfillment on health outcomes. Various types of patient requests were measured, including request for a new medication from a physician. The authors found that previsit trust in physician was an important predictor of request fulfillment and satisfaction.

The Commitment-Trust Theory (Morgan and Hunt, 1994) states that commitment and trust are mediators of successful relationship marketing. A meta-analysis of the antecedents and consequences of trust in a sales context points that trust has a moderate but beneficial influence on the development of positive customer attitudes, intentions,

and behavior (Swan, Bowers, and Richardson, 1999). It has been noted that trust enhances the likelihood of future interactions among parties (Doney and Cannon, 1997).

According the theory of reasoned action it is anticipated that physicians will contribute in the formation of subjective norms. Consumers' will partially arrive at subjective norms depending on their beliefs of how their physician feels about requesting an advertised drug and their motivation to comply with the physicians' expectation. The concern of the present investigation is to examine the distinction between the subjective norm component and consumers' trust in their physician.

It is expected that trust in physicians will have an independent effect on consumers' intention to request the advertised drug. Two arguments are made in support of this relationship. First, it is possible that the physician component in subjective norm may weigh less in consumers' evaluation while forming intentions. For certain consumers the overall subjective norm component may have insignificant contribution. A second and related issue is that consumers' trust in their physician, as an authentic information source might lead them to ask questions about the advertised drug. They may seek the physicians' expert opinion to validate the claims made in the persuasive message. Trust in physician as an expert source may overcome a possible negative subjective norm (with respect to the physician) and contribute towards intention formation. This rationale of trust as a unique antecedent leads to the next hypothesis.

H16: Consumers' trust in their physician will significantly influence their intentions to request the advertised drug.

CHAPTER 4

STUDY DESIGN AND METHODS

This section provides a description of the study design and method used in the research. In the first section operational definitions of various constructs used in the research are developed. In the next section the method of data collection is presented, followed by the analysis section.

4.1. DTC ad

The DTC ad used for this study was of the cholesterol-reducing drug Welchol® (colesevalam HCl). Hypercholesterolemia is a term that refers to the presence of abnormally high levels of total cholesterol, triglycerides or LDL cholesterol in the bloodstream. Lipid disorders are a widespread problem in the United States. More than half of all adult Americans have elevated total blood cholesterol levels. It is estimated that in 1999 there were about 41.3 million American adults with hypercholesterolemia (NHANES III, 1988-94). High LDL-cholesterol is an important risk factor for certain types of heart disease, and a significant number of American men and women need to reduce their total cholesterol levels.

WelChol® (colesevelam HCl) is a non-systemic cholesterol-reducing agent that is available by prescription. Most medications are absorbed from the intestine into the bloodstream and circulate throughout the body where there is the potential to cause

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Welchol® is a registered trademark of Sankyo Pharma.

systemic side effects. WelChol® is nonsystemic, which means that it passes through the body without being absorbed into the bloodstream or metabolized by the liver.

WelChol® has been specifically engineered for affinity, specificity and high capacity for binding to bile acids in the intestine. As WelChol® is eliminated from the body, it removes bile acids with it. Cholesterol, the building block for bile acids, is then drawn from the bloodstream to replenish the depleted bile acid, resulting in an overall lowering of LDL cholesterol in the bloodstream.

WelChol® administered alone or in combination with an HMG-CoA reductase inhibitor (statin), is indicated as adjunctive therapy to diet and exercise for the reduction of elevated LDL cholesterol in patients with primary hypercholesterolemia when diet and exercise alone are inadequate. WelChol® has been widely studied and has been proven to significantly lower cholesterol. A study published in the Archives of Internal Medicine (Davidson, Dillon, Gordon, Jones, Samuels, Weiss, Isaacsohn, Toth, and Burke, 1999) concluded that WelChol® is effective in lowering LDL cholesterol by up to 19%.

Clinical trials have demonstrated that co-administration of WelChol® and statin drugs (Lipitor®/atorvastatin, Mevacor®/lovastatin and Zocor®/simvastatin) can lower LDL cholesterol levels more dramatically than using either therapy alone. There are significant patient populations that are either resistant to statins, intolerant of statins, or uncomfortable with the side effect profile associated with statins. For these patients, Welchol® presents an attractive alternative.

In a study published by The American Journal of Medicine (Knapp, Schrott, Ma, Knopp, Chin, Gaziano, Donovan, Burke, and Davidson, 2001), WelChol® 3.8 g per day

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Lipitor® is a registered trademark of Pfizer Inc; Mevacor® and Zocor® are registered trademarks of Merck & Co., Inc.

combined with Zocor® (simvastatin) 10 mg per day produced an additive effect, resulting in a 42% mean reduction in LDL cholesterol versus 26% reduction seen with Zocor® 10 mg alone. In a clinical study, WelChol® 3.8 g per day combined with Lipitor® (atorvastatin) 10 mg per day, resulted in a 48% average reduction in LDL cholesterol (Welchol® Package Insert).

WelChol® has a favorable safety profile. Since WelChol® is not absorbed into the blood stream, it has few side effects. The most common side effects (>5%) are gas, constipation, infection, upset stomach and headache. Patients who have bowel obstruction should not take WelChol®. It also has a favorable drug-drug interaction profile. In human drug interaction studies, WelChol® had no significant effect on the absorption of digoxin, lovastatin, metoprolol, quinidine, valproic acid or warfarin, some of which are known to interact with other lipid-lowering agents.

WelChol® is available as 625 mg solid tablets. The recommended dose is 6 tablets taken once per day or 3 tablets taken twice per day with meals and a liquid. It is available by prescription only. The U.S. Food and Drug Administration approved WelChol® for marketing in May 2000 and was launched in September, 2000 by Sankyo Pharma. Its promotional spend on DTC ads was $ 0.3 Million in 2001. The DTC ad expenditure of other cholesterol-reducers is shown below (Scussa, 2002).

Brand	Molecule	Company	$ in Million
Zocor®	Simvastatin	Merck & Co.	80.7
Lipitor®	Atorvastatin	Pfizer	47.6
Pravachol®	Pravastatin	Bristol-Myers Squibb	35.6
Lescol® XL	Fluvastatin	Reliant Pharmaceuticals	0.8
Niaspan®	Niacin	Kos Pharmaceuticals	0.8
Welchol®	Colesevalam	Sankyo	0.3

4.2. Operational Definitions and Variables

4.2.1. Behavioral Intentions

Consumers' intention to request WelChol® from their physician was measured using three items on a 7-point semantic differential scale. These items have been used to measure various behavioral intentions and have high reliability. MacKenzie, Lutz, and Belch (1986) used these items to measure consumers' intentions of buying toothpaste and reported a Cronbach's alpha = 0.88 and 0.90 in their two experiments. These items were also used to study consumers' intention to purchase soft drinks and jeans, which yielded an alpha of over 0.95 (Machleit, Allen, and Madden, 1993). Specifically respondents were asked:

My intention to request WelChol® from my physician during the next visit is

Likely	_____	_____	_____	_____	_____	_____	_____	*Unlikely*
	extremely	*quite*	*slightly*	*neither*	*slightly*	*quite*	*extremely*	
Probable	_____	_____	_____	_____	_____	_____	_____	*Improbable*
Possible	_____	_____	_____	_____	_____	_____	_____	*Impossible*

4.2.2. Attitude towards the DTC ad

Attitude towards the DTC ad was measured using ten 7-point semantic differential items. These items were selected so that both the evaluative and affective components of attitude are captured. The selection of the items was guided by Crites, Fabrigar, and Petty (1994), Miniard, Bhatla, and Rose (1990), and Trafimow and Sheeran (1998). The median reliabilities reported are 0.91 and 0.94 for the evaluative and affective scales respectively. Participants responded to each item by checking one of the seven intervals along the 7-point bipolar continuum described by the word pair. These

responses were assigned a value from +3 to –3, where the positive score represents the positive end of the bipolar continuum and the negative score represents the negative end. To measure the evaluative attitude participants were asked:

Now please think only about the advertisement of WelChol® and indicate your opinion about the ad.

Persuasive	_____	_____	_____	_____	_____	_____	_____	*Unpersuasive*
	extremely	*quite*	*slightly*	*neither*	*slightly*	*quite*	*extremely*	
Valuable	_____	_____	_____	_____	_____	_____	_____	*Worthless*
Perfect	_____	_____	_____	_____	_____	_____	_____	*Imperfect*
Informative	_____	_____	_____	_____	_____	_____	_____	*Uninformative*
Useful	_____	_____	_____	_____	_____	_____	_____	*Useless*

The affective component will be measure by asking the participants to respond to the following stem.

The ad of WelChol® makes me feel

Delighted	_____	_____	_____	_____	_____	_____	_____	*Sad*
	extremely	*quite*	*slightly*	*neither*	*slightly*	*quite*	*extremely*	
Happy	_____	_____	_____	_____	_____	_____	_____	*Annoyed*
Pleasant	_____	_____	_____	_____	_____	_____	_____	*Unpleasant*
Excited	_____	_____	_____	_____	_____	_____	_____	*Bored*
Satisfied	_____	_____	_____	_____	_____	_____	_____	*Unsatisfied*

4.2.3. Involvement

In advertising research involvement has been defined, conceptualized and operationalized in various ways (Muehling, Laczniak, and Andrews, 1993). According to Zaichkowsky (1985) the conceptual meaning of involvement is personal relevance to the

stimulus object. The focus of this research is on individuals' involvement that encourages processing of the ad message. The approach used by Laczniak and Muehling (1993) was adopted to categorize subjects into involvement groups on the basis of their involvement or interest in cholesterol management.

It was expected that subjects with higher product class involvement would exhibit more effort in processing the messages in the DTC ad due to their personal relevance. This approach is recommended in situations when subjects are likely to be more *naturally* involved with an advertised message. In addition this approach reduces the artificiality associated with experimentally manipulating personal variables.

Involvement was measured using Zaichkowsky's (1994) Revised Personal Involvement Inventory. This is a ten item 7-point bipolar semantic differential scale that has been empirically validated across various product categories. The reliability of this scale has been found to be over 0.90 and the test-retest reliability was over 0.70 when used to measure involvement across different products and ads. The involvement score will be obtained by adding the ten items, with 10 being the anchor for low involvement and 70 being the anchor for high involvement.

The purpose of this section is to measure your involvement or interest in 'cholesterol management'. To take this measure, we need you to judge WelChol® against a series of descriptive scales according to how you perceive this drug.

To me WelChol® is

Important	_____	_____	_____	_____	_____	_____	_____	*Unimportant#*
Boring	_____	_____	_____	_____	_____	_____	_____	*Interesting*
Relevant	_____	_____	_____	_____	_____	_____	_____	*Irrelevant#*

Exciting _____ _____ _____ _____ _____ _____ _____ *Unexciting*

Means nothing _____ _____ _____ _____ _____ _____ _____ *Means a lot*

Appealing _____ _____ _____ _____ _____ _____ _____ *Unappealing*[#]

Fascinating _____ _____ _____ _____ _____ _____ _____ *Mundane*[#]

Worthless _____ _____ _____ _____ _____ _____ _____ *Valuable*

Involving _____ _____ _____ _____ _____ _____ _____ *Uninvolving*[#]

Not needed _____ _____ _____ _____ _____ _____ _____ *Needed*

 # Indicates item is reverse scored

4.2.4. Attitude towards drug requesting behavior

Attitude towards drug requesting behavior was also measured to represent both the evaluative and affective domains. Ten 7-point semantic differential items were used to measure these two domains. These items were recently used by Bagozzi et al (Bagozzi, Lee, and Van Loo, 2001) to study consumers' intention to donate bone marrow across various cultures. The average reliability of the evaluative and affective items was 0.92 and 0.87 respectively. Respondents were asked to respond to the following stem, where the first five items represent the evaluative domain and the next five items represent the affective domain.

For me, requesting WelChol® from my physician during the next visit can be described as

Rewarding _____ _____ _____ _____ _____ _____ _____ *Punishing*
extremely quite slightly neither slightly quite extremely

Wise _____ _____ _____ _____ _____ _____ _____ *Foolish*

Beneficial _____ _____ _____ _____ _____ _____ _____ *Harmful*

Useful _____ _____ _____ _____ _____ _____ _____ *Useless*

Good _____ _____ _____ _____ _____ _____ _____ *Bad*

Enjoyable _____ _____ _____ _____ _____ _____ _____ *Unenjoyable*

Pleasant _____ _____ _____ _____ _____ _____ _____ *Unpleasant*

Comfortable _____ _____ _____ _____ _____ _____ _____ *Uncomfortable*

Attractive _____ _____ _____ _____ _____ _____ _____ *Unattractive*

Appealing _____ _____ _____ _____ _____ _____ _____ *Unappealing*

4.2.5. Subjective Norm

Four items were used to measure subjective norm towards drug requesting behavior. These measures were adopted from Shimp and Kavas (1984). One item was a standard item as recommended by Fishbein and Ajzen (1975). The other three items were semantic differential items with the following bipolar anchors: wise/foolish, useful/useless, and valuable/worthless. The reliability of these measure reported in the literature is above 0.75. All four items will be measured on a 7-point scale as follows, with scores ranging from +3 to -3.

Most people who are important to me think I

I should _____ _____ _____ _____ _____ _____ _____ *I should not request WelChol® from my physician.*

Most people who are important to me probably consider my requesting WelChol® from my physician to be

Wise _____ _____ _____ _____ _____ _____ _____ *Foolish*

Useful _____ _____ _____ _____ _____ _____ _____ *Useless*

Valuable _____ _____ _____ _____ _____ _____ _____ *Worthless*

4.2.6. Cognitive Structure

Beliefs represent an important element in determining the cognitive structure of an individual. According to Fishbein and Ajzen (1975), the first step in determining the cognitive structure is to identify accessible beliefs. In the present study these accessible beliefs were elicited from a pilot study that comprised of a representative sample of the population. (Details about this elicitation study are presented in the data collection section).

To elicit accessible beliefs participants in the pilot study were first shown the DTC ad of WelChol®. They were given a few minutes to list their thoughts in response to the following questions.

- *What do you think are the advantages of requesting WelChol® from your physician?*
- *What do you think are the disadvantages of requesting WelChol® from your physician?*
- *Is there anything else you associate with requesting WelChol® from your physician?*

The beliefs that were most frequently elicited (modal) in this sample were operationalized as accessible beliefs of the population. These modal accessible beliefs were used to measure the cognitive structure. Respondents were asked two questions with respect to each belief to assess their belief strength and outcome evaluation. The belief strength was assessed using a 7-point bipolar scale with likely (+3) and unlikely (-3) as anchors. The outcome evaluation of the beliefs was assessed with a 7-point bipolar scale with good (+3) and bad (-3) as anchors.

Belief Strength:

By requesting WelChol® from my physician, I will get a prescription drug that can lower my cholesterol by 15-18%.

By requesting WelChol® from my physician, I will get a prescription drug that will not be absorbed in the bloodstream.

By requesting WelChol® from my physician, I will get a prescription drug that does not pass through kidneys or liver.

By requesting WelChol® from my physician, I will get a prescription drug that has some side effects.

Likely _____ _____ _____ _____ _____ _____ _____ *Unlikely*
extremely quite slightly neither slightly quite extremely

Outcome Evaluation:

Lowering cholesterol by 15-18% is

A drug that is not absorbed in the bloodstream is

A drug that does not pass through kidneys or liver is

A drug that has some side effects is

Good _____ _____ _____ _____ _____ _____ _____ *Bad*
extremely quite slightly neither slightly quite extremely

Finally, the product of each outcome evaluation multiplied by the corresponding belief strength was used as a measure of the cognitive structure, which is represented mathematically as follow.

$$C_{beh} = b_i \, e_i$$

where C_{beh} = individual's cognitive structure

b = belief strength

e = evaluation of the outcome

i = specific accessible belief (i=1 to 4)

4.2.7. Normative Structure

According to Fishbein and Ajzen (1975), accessible referents need to be identified to determine the normative structure. A set of model accessible referents were identified from the pilot study. To elicit accessible referents, participants were asked the following questions after they were shown the DTC ad of WelChol®.

- *Are there any individuals or groups who would approve of your requesting WelChol® from your physician?*
- *Are there any individuals or groups who would disapprove of your requesting WelChol® from your physician?*
- *Are there any other individuals or groups who come to mind when your think about requesting WelChol® from your physician?*

Modal accessible referents were used to measure the normative structure by asking respondents two questions with respect to each referent. The normative belief strength was assessed using a 7-point bipolar scale with should (+3) and should not (-3) as anchors. Respondents' motivation to comply was measured by a 7-point scale with not at all (1) and very much (7) as anchors.

Normative Belief Strength:

My spouse/partner thinks that I

My parents think that I

My physician thinks that I

My friends/coworkers think that I

I should ____ ____ ____ ____ ____ ____ ____ *I should not request WelChol® from my physician.*

Motivation to Comply:

Generally speaking, how much do you want to do what your spouse/partner thinks you should do?

Generally speaking, how much do you want to do what your parents think you should do?

Generally speaking, how much do you want to do what your physician thinks you should do?

Generally speaking, how much do you want to do what your friends/co-workers thinks you should do?

Not at all ____ ____ ____ ____ ____ ____ ____ *Very much*

The product of normative belief strength multiplied by the individuals corresponding motivation to comply was operationalized as the normative structure and is represented as follow.

$$N_{beh} = NB_i\ MC_i$$

where N_{beh} = subjective norm

NB = normative beliefs

MC = motivation to comply

i = specific normative belief (i=1 to 4)

4.2.8. Past Behavior

It is unusual for consumers to request WelChol® from their physician if they have already requested or discussed about the drug in previous visits. Alternatively, in situations where consumers have not requested WelChol® from the physician it is not feasible to operationalize past behavior as a measure of having requested WelChol®. Hence drug requesting behavior is considered as an unrepeated behavior and *similar* prior behavior was included as a measure of past behavior.

Sutton (1994) notes that many health-related behaviors are in principle capable of being repeated. This argument is extended in the present context of drug requesting behavior. It is felt that consumers' prior behavior of interacting with their physician regarding treatment options, information about the newly diagnosed medical condition, etc. will be important and might influence in forming behavioral intentions of requesting WelChol®. Simply stated, consumers' prior behavior of initiating conversation with their physician on health-related issues was operationalized as past behavior. Quine and Rubin (1997) have operationalized past behavior using *similar* prior behavior in their research on intentions to take hormone replacement therapy.

Measures of similar prior behavior were adopted from Blamberg, Ajzen, and Schmidt (1999). Respondents were asked to indicate how often they had interacted with their physician in previous visits regarding information about a medical condition, on the drug prescribed by the physician, about various treatment options available. These were measured on a 5-point scale having the following intervals: always, often, occasionally, seldom, never.

Please indicate how often you have asked your physician about the following issues in your earlier visits.

'Information about a newly diagnosed medical condition'

Always	*Often*	*Occasionally*	*Seldom*	*Never*

'Different treatment options available'

Always	*Often*	*Occasionally*	*Seldom*	*Never*

'Drug prescribed by the physician'

Always	*Often*	*Occasionally*	*Seldom*	*Never*

4.2.9. Trust in Physician

Anderson and Dedrick (1990) developed the Trust in Physician Scale and reported a Cronbach's alpha of 0.90 and 0.85 in two studies involving diabetic male patients from a VA medical center. Thom et al (Thom, Ribisl, Stewart, Luke and the Stanford Trust Study Physicians, 1999) evaluated and validated the Trust in Physician Scale in a more general primary care population of male and female patients. The scale showed high internal consistency (Cronbach's alpha = 0.89) and good 1-month test-retest reliability (Intraclass correlation coefficient = 0.77). In the present study this scale was used to operationalize consumers' trust in their physician.

The Trust in Physician Scale has 11-items measured on a 5-point Likert scale where 1=strongly disagree, 2=disagree, 3=uncertain, 4=agree, and 5=strongly agree. The items used in the scale were as follows where # denotes a reverse scored item.

1. *I doubt that my doctor really cares about me as a person.*[#]
2. *My doctor is usually considerate of my needs and puts them first.*
3. *I trust my doctor so much I always try to follow his/her advice.*
4. *If my doctor tells me something is so, then it must be true.*
5. *I sometimes distrust my doctor's opinion and would like a second one.*[#]
6. *I trust my doctor's judgments about my medical care.*
7. *I feel my doctor does not do everything he/she should about my medical care.*[#]
8. *I trust my doctor to put my medical needs above all other considerations when treating my medical problems.*
9. *My doctor is well qualified to manage (diagnose and treat or make an appropriate referral) medical problems like mine.*
10. *I trust my doctor to tell me if a mistake was made about my treatment.*
11. *I sometimes worry that my doctor may not keep the information we discuss totally private.*[#]

The total score was obtained by adding all items and transforming the total to a 0 to 100 scale, where 0 would be the lowest possible score and 100 the highest possible trust score. Thom et al slightly modified one item (item 9) from the original scale for its appropriateness to a primary care setting.

4.3. Data Collection

4.3.1. Elicitation Study

To elicit accessible beliefs, a convenience sample of 12 consumers with high cholesterol was used. The convenience sample was recruited from the members of staff

of the College of Pharmacy, University of Georgia. Respondents were notified about the study objective by e-mail and were solicited for participation. Respondents having a health-care education background were excluded. Respondents who volunteered were personally contacted and explained the purpose of the study. A written informed consent was obtained from each respondent before the elicitation exercise. They were shown the Welchol® ad and were asked the open-ended questions regarding their beliefs and referents as described above.

4.3.2. Main Study

The population of interest for this research study was adults having high cholesterol. Data was collected using a cross-sectional survey using a self-administered questionnaire from consumers with high cholesterol. The sampling frame consisted of over 220,000 consumers who had been diagnosed with high cholesterol. This sampling frame was a nationally representative list which is compiled from prescription records, mail order purchase information, 1-800 # respondents, consumer surveys and questionnaires.

Power analysis was conducted to estimate the minimum sample size required to establish the statistical validity of the estimated models. A recent approach offered by MacCallum, Browne, and Sugawara (1996) was used to calculate the sample size. Using a 95% confidence interval to achieve a power (i.e. ability to detect and reject a poor model) of 0.80 a sample size of 401 is necessary. A difference of 0.01 in the root mean square error of approximation was used as an indicator of effect size for 251 degrees of freedom. This also satisfies the criteria that the sample size should be atleast five times

the number of free parameters in the model including the error terms (Bentler and Chou, 1987). Assuming 20% missing values and 10% response rate 5000 consumers were selected from this sampling frame using a simple random technique.

Participation in the study was voluntary, but to increase the response rate an advance notice postcard was mailed to consumers in January informing them about the study and expecting the survey materials by mail within the next week. Data collection was conducted after a formal approval of the research study was obtained from the University of Georgia's Institutional Review Board.

The main survey was mailed to the consumers in the first week of February by first-class mail which included the Welchol® ad, questionnaire along with a cover letter, and a business reply mail. The cover letter contained information about the research, anonymity of responses, and implied consent. It also contained contact information of the principal investigator and the University of Georgia's Human Subjects Office. The questionnaire contained measures of attitudes towards the DTC ad and drug-requesting behavior, involvement, subjective norms, cognitive and normative structure, past behavior, trust in physician, behavioral intentions as described above. Demographic information related to gender, age, income, region, and education were also collected. Personal identifiers like name or SSN were not collected.

The returned questionnaires were recorded in a database file using Visual FoxPro v6.0 by a trained data entry person and the principal investigator. Using descriptive statistics, errors in the database file were corrected after comparing with the responses in the questionnaire. In addition, 5% questionnaires were selected at random and manually

matched with the data in the file. All the questionnaires were kept under lock and key and the database file was protected using a password.

4.4. Data Analysis

The research hypotheses were tested using structural equation models with latent variables. Structural equation modeling has the advantage of estimating multiple and non-recursive relationships simultaneously. It also has the ability to account for measurement error in the estimation process thereby representing theoretical constructs into the analyses.

According to established conventions (Bollen, 1989) observed variables (x and y) are represented in square boxes. These are also known as items, indicators or manifest variables. The latent constructs are denoted by circles and greek symbols (ξ and η) and are also known as unobserved variables, concepts or factors.

The overall structural equation model consists of two parts: a measurement model and a structural model. The measurement model specifies the relationship between the observed variables and latent constructs. It estimates the contribution of each indicator to the latent construct thereby estimating the reliability of the items. The structural model specifies the inter-relationships between the independent (latent exogenous) variables and dependent (latent endogenous) variables.

The analyses were carried out using the covariances among the observed measures (Cudeck, 1989). The use of a covariance matrix has an advantage of providing comparisons between different samples (i.e. high vs. low involvement groups). The use of a covariance matrix is also in line with the objective of the research which involves

'testing of a theory' (Hair, Anderson, Tatham, and Black, 1998) and to explain the total variance of the focal construct viz. consumers' drug requesting behavior. LISREL 8.53 was used for analysis and maximum likelihood will be used to estimate the measurement and structural parameters.

4.4.1. Measurement Model

According to Joreskog (1993) before testing the structural model it is essential to test the measurement models to confirm that the chosen indicators measure the intended construct. A confirmatory factor analysis was conducted on the latent variables, which is represented as follows.

$$x = \Lambda_x \xi + \delta$$

$$y = \Lambda_y \eta + \varepsilon$$

where x = vector of observed exogenous variables (q x 1)

Λ_x = matrix of factor loadings of latent exogenous factors (q x n)

ξ = vector of latent exogenous factors (n x 1)

δ = vector of error variables of x (q x 1)

y = vector of observed endogenous variables (p x 1)

Λ_y = matrix of factor loadings of latent endogenous factors (p x m)

η = vector of latent endogenous factors (m x 1)

ε = vector of error variables of y (p x 1)

A scale was assigned to the latent variable by fixing the first indicators' factor loading to unity in the respective Λ_x and Λ_y matrices. This method scales the latent variable to the same units of measurement as the observed variables and helps in

interpreting the structural parameter estimates (Joreskog and Sorbom, 1996). Since for the latent variable 'trust' a scaled score was used it was corrected for its unreliability in measurement. This was achieved by fixing the factor loading equal 1.0 and the error variance equal to ((1-reliability) * (variance of the scale score)).

The fundamental approach in structural equation modeling is to minimize the difference between the sample covariances (S) and the covariances (Σ) predicted by the model (Bollen, 1989). For the measurement model the model-implied covariances among the observed variables was calculated as follows.

$$\Sigma_x = \Lambda_x \Phi \Lambda_x' + \Theta_\delta$$

$$\Sigma_y = \Lambda_y \Psi \Lambda_y' + \Theta_\varepsilon$$

where Σ_x = model implied covariance matrix of x variables (q x q)

Φ = matrix of exogenous factor covariances (n x n)

Θ_δ = matrix of covariances of error variables of x (q x q)

Σ_y = model implied covariance matrix of y variables (p x p)

Ψ = matrix of endogenous factor covariances (m x m)

Θ_ε = matrix of covariances of error variables of y (p x p)

4.4.2. Structural Model

After assessing the measurement model the structural relationships were tested. The structural model of the latent exogenous and endogenous variables and the implied covariance matrix of the observed variables are represented as follows.

$$\eta = B\eta + \Gamma\xi + \zeta$$

where B = coefficient matrix of the latent endogenous variables (m x m)

Γ = coefficient matrix of the latent exogenous variables (m x n)

ζ = vector of latent error variables in the structural relationships between η and ξ (m x 1)

$$\Sigma = \left[\begin{array}{c|c} \Lambda_y[(I-B)^{-1}(\Gamma\Phi\Gamma' + \Psi)(I-B)^{-1\prime}]\Lambda_y' + \Theta_\varepsilon & \Lambda_y(I-B)^{-1}\Gamma\Phi\Lambda_x' \\ \hline \Lambda_x\Phi\Gamma'(I-B)^{-1\prime}\Lambda_y' & \Lambda_x\Phi\Lambda_x' + \Theta_\delta \end{array}\right]$$

The research hypotheses on the cognitive and affective consequences of DTC ads were tested using a multi-sample analysis. The sample was split into low and high involvement groups on the basis of the median summated score of the involvement items. This approach has been used in studies when it is difficult to experimentally manipulate personal variables (Homer, 1990; Laczniak and Muehling, 1993). Before comparing the structural parameter estimates between the high and low involvement groups a test of measurement invariance was conducted by comparing a series of nested models using the Vandenberg and Lance (2000) criteria. It is essential to establish measurement invariance between the two groups to rule out any observed differences in the structural parameter estimates due to difference in reliability, or variability in the factor structure.

The interrelationships among the exogenous and endogenous variables were investigated as shown in figures 6, 7, and 8. The significance of structural parameter estimates were tested at $\alpha = 0.05$ level. The null hypothesis states that the parameter is not present in the proposed model. A significant difference at $\alpha = 0.05$ will be used as evidence to reject the null hypothesis suggesting that the parameter increases the model fit and the relevant path should be included in the model.

4.4.3. Model Evaluation

Adequacy of the models was determined using the χ^2 goodness-of-fit statistic. The objective of the χ^2 goodness-of-fit is to attain a non-significant statistic, since the statistic measures the difference between the observed covariance matrix and the one reproduced by the model. The level of statistical significance indicates the probability that the differences between the two matrices are due to sampling variation. Failure to reject the hypothesis of no difference (at $\alpha = 0.05$) indicates that the proposed model fits the data.

Since the power of χ^2 test is based on sample size, there is a likelihood of rejecting any model as the sample size increases (Hu and Bentler, 1993). Therefore in addition to the χ^2 goodness-of-fit statistic the Standardized Root Mean Square Residual (SRMSR; Bentler, 1995), Root Mean Square Error of Approximation (RMSEA; Steiger, 1990), Tucker-Lewis Index (TLI; Tucker and Lewis, 1993), and Comparative Fit Index (CFI; Bentler, 1990) were also used to assess the model fit.

The SRMSR is the average difference between the predicted and observed covariances in the model based on standardized residuals. The smaller the SRMSR the better the model fit. Hu and Bentler (1999) recommended a value of 0.08 or less as excellent fit. However 0.10 has been used as an upper limit for a good fitting model (Medkser, Williams, and Holahan, 1994).

A fit index that attempts to correct the effect of sample size on χ^2 is the RMSEA, which measures the discrepancy per degree of freedom. The RMSEA does not require a null model for its computation and is an independent fit measure. Values upto 0.08 represent reasonable errors of approximation (Joreskog and Sorbom, 1996). Recently Hu

and Bentler (1999) proposed a critical value of 0.06 or less to conclude that there is a relatively good fit between the hypothesized model and the observed data.

The TLI, also known as the nonnormed fit index (NNFI), combines a measure of parsimony into a comparative index between the proposed and the null model. This results in a value ranging from 0 to 1. By convention values of 0.90 or greater are recommended (Marsh and Hau, 1996). However Hu and Bentler (1999) have suggested NNFI > = 0.95 as the cutoff for a good model fit. It is one of the fit indices that is less affected by sample size.

The last of the fit index, CFI, is more appropriate in a model development strategy or when the sample size is small (Ridgon, 1996). CFI compares the existing model with a null model that assumes that all the latent variables are uncorrelated. This incremental fit index is also less affected by sample size and values of 0.90 or more are considered satisfactory (Bentler, 1990).

4.4.4. Model Building and Modification Strategy

The aim of this research study is to assess a series of inter-relationships among the antecedents of consumers' drug requesting behavior. The purpose is not to merely validate the persuasive mechanism of A_{ad} or the theory of reasoned action in forming behavioral intentions. Joreskog (1993) describes three strategies for model construction and development: strictly confirmatory, model comparisons, and model generation. It is believed that confirmation of a model implies exclusive validation of the model (Biddle and Marlin, 1987). However, Mulaik and James (1995) state that evidence does not validate a model because there can be other possible explanations that are acceptable.

MacCallum (1995) recommend using a 'model comparison' strategy for model specification. This approach was adopted and competing models were hypothesized. It is emphasized that the 'best-fitting' model among the competing set of models is not the true model. It is the best-fitting model because it is not disconfirmed by the data. It only demonstrates that the model provides a best possible explanation of consumers' intention to request a drug from their physician.

Three competing models were developed to study the inter-relationships among the antecedents. In the first model (Figure 6) attitude is construed as a single factor. The multidimensionality of attitude is captured in subsequent models. In the second model (figure 7) attitude is represented with two distinct but correlated factors: evaluative and affective. Using this representation the cognitive and affective mechanisms of persuasion are modeled in a slightly different manner. The cognitive process is believed to change the underlying beliefs which in turn changes A_{beh}. We argue that only the evaluative component of attitude is responsible for the cognitive mechanism. In contrast, the affective mechanism suggests no change in the underlying cognitive structure and refers to emotional responses arising after exposure to the stimulus. Against this point of view we contend a direct relationship from affective A_{ad} to affective A_{beh}.

Though model two yields relevant distinction between the evaluative and affective components it has a major drawback. Both the evaluative and affective components are modeled as antecedents of behavioral intentions giving rise to multicollinearity. This issue was addressed in model three by synthesizing a second-order attitude factor from the two first-order evaluative and affective factors (figure 8). This representation states that consumers may differ in their formation of evaluative and

affective attitudes which contributes differentially in the overall attitude formation. The second-order factor directly influences behavioral intentions.

CHAPTER 5

RESULTS

5.1. Elicitation Study

A convenience sample of 12 subjects was recruited from the members of the College of Pharmacy, A total of 23 different but related beliefs were elicited. A content analysis was carried out and these beliefs were clustered together on the basis of their similarity. A frequency distribution of these beliefs is presented in table 1. For significant others, a total of 22 referents were elicited which were clustered into eight groups. A frequency distribution of the elicited referents is presented in table 2. Based on the frequency distribution the top four most frequently elicited beliefs and referents provide the basis for assessing the cognitive and normative beliefs in the main study.

5.2. Main Study

5.2.1. Response Rate

A total of 5000 surveys were mailed of which 37 were undeliverable due to incomplete and change of address. We received 903 questionnaires for an 18% response rate. We eliminated 25 surveys for blank/missing sections. A list-wise deletion method was used to delete 134 cases with missing values for a final sample size of 744 respondents.

5.2.2. Demographic Characteristics

The demographic profile of the respondents is presented in table 3. Of the final 744 respondents 41% were male, 92% were Caucasian, and 3% were African American. The mean age of the sample was 62 years (SD=12.0; range: 25-88). 76.4% of the respondents were married, 75% had completed atleast an undergraduate degree and the median household income was $71,000. Approximately 14% of the respondents had heard or seen the Welchol® ad before.

5.2.3. Assumptions

The items were assumed to be approximately normally distributed since both the skewness and kurtosis values were < |2.0| (table 6). Only two items had kurtosis > |2.0|. Subsequently, we computed the relative multivariate kurtosis (= 1.401) which indicated that the data was multivariately normally distributed.

5.2.4. Measurement Model Fit

One cognitive structure item was dropped from the analysis because it had insignificant and low factor loadings. On visually examining the items measuring cognitive beliefs we found that three items were related to the benefit aspect of the drug and the item causing the misfit was related to safety profile of the drug. Cronbach alpha's of all the scales indicated very good internal consistencies since all α's (table 8) were greater than .81.

Attitude as a unidimensional construct was rejected due to high RMSEA (.085). The fit indices of the measurement models (Table 10) supported the multidimensional

structure of attitude. The model with attitude as two distinct but correlated factors had RMSEA = .055; SRMR = .050; CFI = .99; TLI = .98 and the model with attitude as a second-order factor had RMSEA = .057; SRMR = .054; CFI = .99; TLI = .98.

The construct reliabilities of all the constructs exceed .83 above the recommended level of .7 (Hair, Anderson, Tatham, and Black, 1998) indicating that individual indicators are all consistent in their measurements. The variance extracted measure reflects the overall amount of variance of the each indicator that is accounted by its latent construct. All the constructs had a value of .58 or more which exceeded the recommended level of .5 (Hair, Anderson, Tatham, and Black, 1998), suggesting that more than half of the variance of the indictors is accounted by the constructs. These two measures along the Cronbach's alpha imply that the items are related to their specific constructs.

To demonstrate the discriminant validity of the evaluative and affective dimensions of attitude, we estimated a model constraining the correlation of the two dimensions equal to one. The constrained model had a significantly worse fit than the unconstrained model ($\Delta\chi^2(2) = 47.31$, $p < .05$). Using this empirical evidence of discriminant validity of the evaluative and affective dimensions of attitudes we parceled the five items into two random sets, each containing an average score of two and three items. Parceling of multiple items into sets leads to smoothing of random error, reduces the number of parameters to be estimated and ensures the critical ratio of cases to parameters (Bagozzi, Lee, and Van Loo, 2001).

We again tested the assumptions of the parceled items (table 7) and found evidence that the parceled indicators were also approximately normally distributed. Since

two parceled indicators had kurtosis > |2.0|, we computed the relative multivariate kurtosis (= 1.317) which indicated that the parceled data was multivariately normally distributed. The internal consistency measures of the parceled indicators estimated by Cronbach's alpha (table 9) and composite reliability along with the variance extracted suggest that the parceled indicators also are good measures of the hypothesized constructs.

The goodness-of-fit indices (table 10) for the parceled indicators also reflected similar outcomes as that of the individual items. The model with a unidimensional structure of attitude is disconfirmed by the data (RMSEA=.077). The fit indices of the models with multidimensional attitudes suggest that attitude is composed of two distinct elements. The model with two attitudinal factors had RMSEA=.049; CFI=.99; TLI=.99; SRMR=.048 and the model with attitude as a second-order factor comprising two first-order factor has RMSEA=.052; CFI=.99; TLI=.99; SRMR=.051.

5.2.5. Structural Model Fit

The structural models were estimated for all the three models characterizing the unidimensional and multidimensional nature of attitudes. The fit indices of the structural model one which represents the unidimensional nature of attitudes has a very high RMSEA (.077) and is rejected (table 12). The goodness-of-fit indices of the structural model two, where attitude is characterized as two distinct but correlated factors, present sufficient evidence to reject the model. This model fails to meet the cut-off criteria of RMSEA (.079) and SRMR (.240). A high RMSEA indicates an over-fitting model since RMSEA penalizes complex models by incorporating the degrees of freedom. With the

representation of attitude as a two factor model each affecting behavioral intentions separately there are more free parameters and fewer degrees of freedom leading to high RMSEA.

On inspecting the residuals we note that they are unusually high. Given the model complexity it was expected that this model will yield small SRMR. However, the high standardized residuals (SRMR = .240) indicate a large discrepancy between the predicted and observed covariances. This discrepancy can be attributed to multicollinearity issues due to high correlation between the two dimensions of attitudes. The high SRMR in conjunction with a high RMSEA disconfirms this model on grounds of misspecification and lack of fit. In light of the hypothesized competing models we abstain from the exploratory method of identifying and modifying individual parameters to improve model fit.

The model with attitude as a higher second-order factor fits the data very well. The RMSEA (.048) and SRMR (.055) are below the threshold criteria. The CFI, which compares the model with a null model with uncorrelated latent variables, has a value of .99 suggesting a very good fit. This fit is further supported by TLI (.99) which combines a measure of parsimony when comparing with the null model. Convergence was achieved after 77 iterations with all parameter estimates being in the right direction. In an attempt to resolve a heywood case the model was respecified and a proper solution was obtained by constraining the error variance of evaluative behavior to a very small number (Dillon, Kumar, Mulani, 1987). The factor loadings of this model are presented in Table 11. All the factor loadings are significant and high.

A distinction between model two and model three is the number of paths from attitude to behavioral intentions. In model three the correlation between the two dimensions of attitude is modeled as a second order factor which directly affects intentions. This is a parsimonious method of explaining the relationship between attitudes and intentions. We now interpret the parameter estimates of model three (table 13).

5.2.6. Multidimensionality of Attitudes

A second-order factor structure for attitude fits the data very well. A_{ad} and A_{beh} are both comprised of evaluative and affective dimensions. Since these two dimensions pertain to the same ad or behavior they are coupled in memory together and this covariation is explained fully by their regression on the second-order factor. A_{ad} is more influenced by the affective feeling generated due to the ad ($\beta = .92$, $t = 27.01$, $p < .05$) when compared to consumers' evaluation of the messages within the ad ($\beta = .80$, $t = 22.20$, $p < .05$). A relatively greater influence is exercised by the evaluative dimension in the composition of A_{beh} ($\beta = .90$, $t = 16.17$, $p < .05$) than the affective dimension ($\beta = .76$, $t = 17.32$, $p < .05$). This reversal in explaining the covariation can be attributed to the higher cognitive involvement in A_{beh} formation.

5.2.7. Cognitive and Affective Consequences of DTC Ads

When consumers have a favorable attitude after evaluating the content in an ad there is a positive impact ($\beta = .50$, $t = 11.17$, $p < .05$) on their beliefs and outcomes about requesting the drug from their physician. Since the relationship from cognitive structure to evaluative-A_{beh} is not significant the cognitive process of persuasion is partially

supported. Further, A_{ad} does not explain any variability of behavioral intentions ($\beta = .07$, $t = 1.10$, $p < .05$) suggesting that the effect of A_{ad} is mediated through A_{beh}. Affective-A_{ad} has a favorable impact on affective-A_{beh}. This supports the non-belief route of persuasion. Positive feelings generated after exposure to the as are transferred to A_{beh} by generating favorable feelings or emotions about drug requesting behavior.

5.2.8. Consequences of DTC Ads: Low and High Involvement Groups

The total sample was split into two groups of low and high involvement on the basis of the involvement score. The mean involvement of the total sample was 54.0 (SD = 8.8; range: 10-70). The internal consistency reliability as measured by Cronbach's alpha for the involvement scale was .86. The low involvement group had 387 respondents with a mean involvement of 47.3 (SD = 6.0; range 10-54) and the high involvement group had 354 respondents with a mean involvement score of 61.2 (SD = 4.8; range: 55-70).

An omnibus test of the covariances matrices was conducted to ensure the measurement equivalence of the constructs in the low and high involvement groups. The goodness-of-fit indices reveal an overall good fit (RMSEA = .05 with a 90% CI: .044-.057; CFI=0.99; and NNFI=0.98). This exceeds the standards for declaring a good fit by Vandenberg and Lance (2000). A good fit indicates that measurement equivalence exists and the constructs are measures invariantly across the low and high involvement groups.

We developed nested models to evaluate for differences in the cognitive and affective routes of persuasion in the low and high involvement groups. The results (table 14) indicate good fit of the structural models. We compared the nested models using

difference in chi-square test and difference CFI. On comparing the invariance of the cognitive paths with the baseline model (model 1) we find that the difference in chi-square is significant ($\Delta\chi^2(3) = 3.7$, $p < .05$). Also the change in CFI is less than 0.01 (Cheng and Rensvold, 2002). A similar result was obtained after comparing the invariance of the affective paths with the baseline model (model 3). The difference in chi-square was significant and the difference in CFI was less than 0.01 ($\Delta\chi^2(2) = 0.3$, $p < .05$). Both these results indicate that the cognitive and affective paths are invariant across the two groups. In other words the persuasive mechanism of A_{ad} is similar for consumers with low or high levels of involvement towards their cholesterol management.

5.2.9. The Theory of Reasoned Action

The theory of reasoned action is helpful in predicting behavioral intentions. A favorable attitude towards drug behavior ($\beta = .28$, $t = 3.50$, $p < .05$), and subjective norm ($\beta = .45$, $t = 8.03$, $p < .05$) significantly enhance consumers' intention to request the drug from their physician. Subjective norm has more influence on intentions than consumers' attitudes. Contrary to the hypothesized relationship, the evaluate-A_{beh} was not determined by consumers' cognitive structure ($\beta = .00$, $t = .02$, $p > .05$). However, a significant positive relationship is observed between normative structure and subjective norm ($\beta = .43$, $t = 11.39$, $p < .05$).

We found partial evidence to support interdependency and crossover effects among the TRA model components. A favorable evaluative-A_{beh} ($\beta = .50$, $t = 12.26$, $p < .05$) and cognitive processing of individual beliefs ($\beta = .07$, $t = 3.22$, $p < .05$) has a direct influence in the formation of subjective norms. No crossover relationship was observed

from subjective norm ($\beta = .06$, $t = 1.04$, $p > .05$) and normative structure ($\beta = .04$, $t = .77$, $p > .05$) to evaluative-A_{beh}. In fact consumers' evaluative-A_{beh} is not influenced by any components of the model.

5.2.10. Past Behavior and Trust in Physician

Consumers' behavioral intention formation is favorably enhanced by their past interactions with the physician ($\beta = .06$, $t = 2.21$, $p < .05$). This result is similar to the results obtained in predicting other health-related behaviors. Higher trust in a physician decreases the likelihood ($\beta = -.10$, $t = -3.35$, $p < .05$) of forming intentions to request for a prescription of the advertised drug. When greater trust is ensued in a physician, consumers are less likely to participate in the decision making process of prescription selection. There is no effect of trust in the formation of consumers' subjective norms ($\beta = -.01$, $t = -.38$, $p > .05$).

CHAPTER 6

DISCUSSION

The purpose of this study was threefold. One, to address the belief-based and non-belief based process of persuasion of DTC ads. Two, to build on the distinction between cognitive and affective components of attitude, and determine the appropriate method of modeling these distinct factors. Third, to test the utility of TRA in understanding consumers' intention to request an advertised drug. We also augmented the TRA by testing the interdependency and crossover effects among the model components. Further we addressed the issue of omitted variable bias by expanding TRA and included attitude towards DTC ads, past behavior/habit, and trust in physician as potential predictors. This chapter discusses the overall findings of the research hypotheses, the specific limitations that were inherent in the present study, and the future research that needs to be conducted to validate and expand upon the results of this analysis. The discussions presented are specific to consumers with high-cholesterol.

6.1. Discussion

6.1.1. Multidimensionality of Attitudes

Our results reflect the multi-dimensional nature of attitudes and replicate the findings of Bagozzi et al (Bagozzi, Lee, and Van Loo, 2001). The results presented here indicate that attitudes towards an ad or a behavior are comprised of two distinct elements. Consumers' use rationale and judgment to process relevant information and arrive at

cognitive evaluation of the attitude object. Consumers also generate favorable or unfavorable emotive responses, feeling, and thoughts in relation to the attitude object.

Our study did not support the unidimensional representation of attitudes. The multidimensionality depiction suggests that consumers may not exhibit uniform assessment of the evaluative and emotive responses generated towards the attitude object. In other words, some consumers may have a favorable evaluative and emotional response whereas other consumers may have a positive evaluative opinion about the attitude object but could have generated negative feelings towards it. In other cases, when consumers have limited potential for evaluation they either could have neutral or negative belief perceptions about the attitude object and possible form an attitude just on the basis of expressive nature of the attitude object. A lack of consistency in correlation leads to rejecting the unidimensional depiction of attitudes.

However, as noted in the previous studies we find that these two attitudinal components are not totally independent. The covariation among these components is best represented by a second-order dimension of attitude. The differential impact of the evaluation and affective components on the overall attitude depends on the attitude object. Our study demonstrates that modeling attitude as a second-order factor is statistically superior and parsimonious representation of the relationship between attitude and behavioral intentions.

6.1.2. Cognitive and Affective Consequences of A_{ad}

We note that DTC ads change consumers' beliefs and attitudes by two mechanisms. In the belief-based process of persuasion, consumer's process information

contained about the product in the ad. A favorable evaluation of the ad message leads to a positive change in their underlying belief structure. They use reasoning and judgment to evaluate the outcomes associated with their beliefs. However our study failed to support a relationship between cognitive structure regarding drug requesting behavior and attitude formation. It seems that favorable attitudes formed towards requesting a drug are independent of favorable or unfavorable changes in the underlying beliefs and their outcomes. This absence of relationship could be due to just a one time exposure to the ad.

The influence of affect generated after seeing an ad on creating favorable affective attitudes towards requesting the drug from a physician underscores the non-belief based route of persuasion. From the classical conditioning theory, in the absence of cognitive processing, a mere liking of the ad leads to the development of favorable attitudes towards requesting the advertised drug. In this route consumers do not assess the relevance and usefulness of the drug for their treatment. From the advertisers perspective to increase the persuasiveness DTC ads should have a mix of information and appeal to change consumers' underlying beliefs and create favorable attitude towards requesting the drug.

6.1.3. The Theory of Reasoned Action

Our results regarding the TRA are particularly useful in predicting consumers' intentions of requesting the advertised drug from a physician. The qualitative pilot study revealed that consumers concentrate on the benefit and side-effects messages of the drug. Issues such as percentage of cholesterol reduction, drug not being absorbed in the blood stream and not passing through kidneys and liver were the most frequently elicited beliefs

by the consumers. They evaluate these beliefs and the outcomes associated with these beliefs to make an overall assessment of the advertised drug.

Consumers' attitudes and social pressure determine their intentions to request the advertised drug from a physician. Subjective norms exercise a larger influence in shaping intention formation than consumers' attitudes. Consistent with the theory, subjective norms are formed after evaluating the normative beliefs and the outcomes associated with these normative beliefs. Subjective norms mediate the influence of normative structure on behavioral intentions. Consumers evaluate the normative beliefs of important referents like parents, spouse/significant others, physician, and friends/co-workers on their requesting behavior. If these evaluations are favorable and positive they are more inclined to discuss about suitability of the advertised drug from a physician during their next visit. The inclusion of common referents in DTC advertisements could make them more persuasive.

Our results failed to demonstrate a link between cognitive beliefs and evaluative attitude formation. Since the print media is a self paced media, consumers probably did not focus on the informational aspects of the drug in the ad. Using media such as the television and radio could probably be more effective in conveying the benefits and safety messages of the drug. The absence of relationship between cognitive beliefs and evaluative attitudes could also be due to one time exposure to the ad. In-depth studies are required that manipulate different types of media and multiple exposures and evaluate the impact on attitude formation.

Our analysis validates the presence of crossover effects in the formation of subjective norms. Normative beliefs are important in the formation of subjective norms,

but cognitive beliefs are also responsible in evaluating the social outlook of requesting a drug. This crossover effect supports the 'false consensus' notion (Ross, 1977) that individuals personal beliefs lead them to infer thoughts and opinions of their referent groups. Consumers also attribute their own attitudes as attitudes held by others. Note that the impact on subjective norms via evaluative-A_{beh} was the largest followed by normative and cognitive beliefs. Thus, individuals evaluate both their cognitive and normative beliefs, but consider and relate social norms from their own internal predispositions regarding the behavior.

6.1.4. Role of Past Behavior and Trust in Physician

We made adjustments to the TRA by including two important predictors of behavioral intentions. Consistent with earlier studies (Bagozzi, 1981b, Bentler and Speckart, 1979) we find that consumers' prior interaction with a physician influences future intentions in drug selection process. This direct relationship suggests that outcomes of previous interaction with a physician generate favorable intentions to repeat similar behaviors. Individuals who exhibit repetitive behavior there is less cognitive burden on active information processing, making future similar behaviors non-volitional. Hence when there is a co-activation of a similar behavioral situation, association between the past actions and present situation is elicited which serves as a source of habitual response in shaping intentions. In such stable behavioral contexts, in addition to the psychosocial elements, past behavior uniquely explains the variance of intentions making it an useful addition to the theory of reasoned action.

Consumers' trust in a physician has a negative influence on their drug requesting behavior. This is contrary to the trust relationship observed in the marketing discipline, specifically observed in the buying-selling situation. In the present context of selecting a drug, the physician is the final deciding authority. When consumers have faith in their physician's competence, they are more confident with the physician's decisions and unquestionably accept the prescribed therapy. This finding has important implications on the patient-physician relationship.

Consumers collect and value information pertaining to their health and treatment. Though DTC ads encourage patients to participate in their heath care decision making process, patients are likely to request the drug only if they are not confident with their physicians' abilities. In managed care settings when patients encounter different physicians, who often evaluate and prescribe therapies in the shortest time, patients are not able to discern the physicians' competence. In such environment, it is likely for patients to debate the physicians' drug selection process by requesting a particular prescription. Trust appears to be an important predisposing physician characteristic that stimulates patient participation in health care decision making.

6.2. Conclusions

This research examined the psychosocial antecedents of consumers' drug requesting behavior. Favorable attitudes and subjective norms lead consumers to form intentions to request the advertised drug from a physician. It also appears that consumers who trust their physician are less likely to make a request. However consumers' prior interactions with a physician make them more likely to interact in the future about the

advertised drug. This research demonstrates a positive crossover effect among TRA model components. Consumers deduce inferences about important referent others on the basis of their own beliefs and attitudes. The study also supported the multidimensionality of attitudes and partially supported the dual route of persuasion of A_{ad} on consumers.

6.3. Limitations and Future Research

The contributions of this research have the potential to enhance the knowledge of psychological factors affecting consumers' intentions to request an advertised drug from a physician. However, limitations of this research needs to be considered while making policy decisions. First, our study only accounts for the variability on behavioral intentions and not overt behavior. A common limitation associated with cross-sectional data is the reliability of the causal relationships hypothesized in the model. For example, the measures of past interactions with a physician were retrospectively elicited and are possibly affected by recall bias. Future research should examine the inter-relationships among the model components using longitudinal designs.

Though we tried to maximize the response rate by an advance notification of the study to consumers, we believe that our sample could have been affected by non-response bias. We believe that opinions of non-responders might be different from the responders affecting the strengths of certain relationships. Non-response bias can be decreased in future studies by encouraging participation through monetary or non-monetary incentives. Participants indicated their responses using a self-reported questionnaire. There was no control on their response patterns which could have been affected by

situational factors. Social desirability could have affected the responses on some measures.

Our study did not demonstrate the moderating effect of involvement on attitude formation. Since our sample consisted of consumers who were diagnosed with high cholesterol they were highly involved in managing their cholesterol levels. Hence the results about the effect of involvement should be interpreted with caution. Future studies should manipulate involvement while researching the impact of involvement on attitude formation.

The items used to measure the theoretical constructs in this research were guided on the basis of their established psychometric properties. Nonetheless, there is a potential of method bias in measurement since all item were designed using semantic differential. Ajzen (2002) has suggested numerous ways of measuring attitude which should be used to get a multi-faceted assessment of attitude in future studies. Our final model is the best-fitting model among a set of three competing models. Future research should consider other factors that can improve the explanatory power of the current model and further evaluate its impact on consumers' health.

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APPENDICES

APPENDIX A

FIGURES

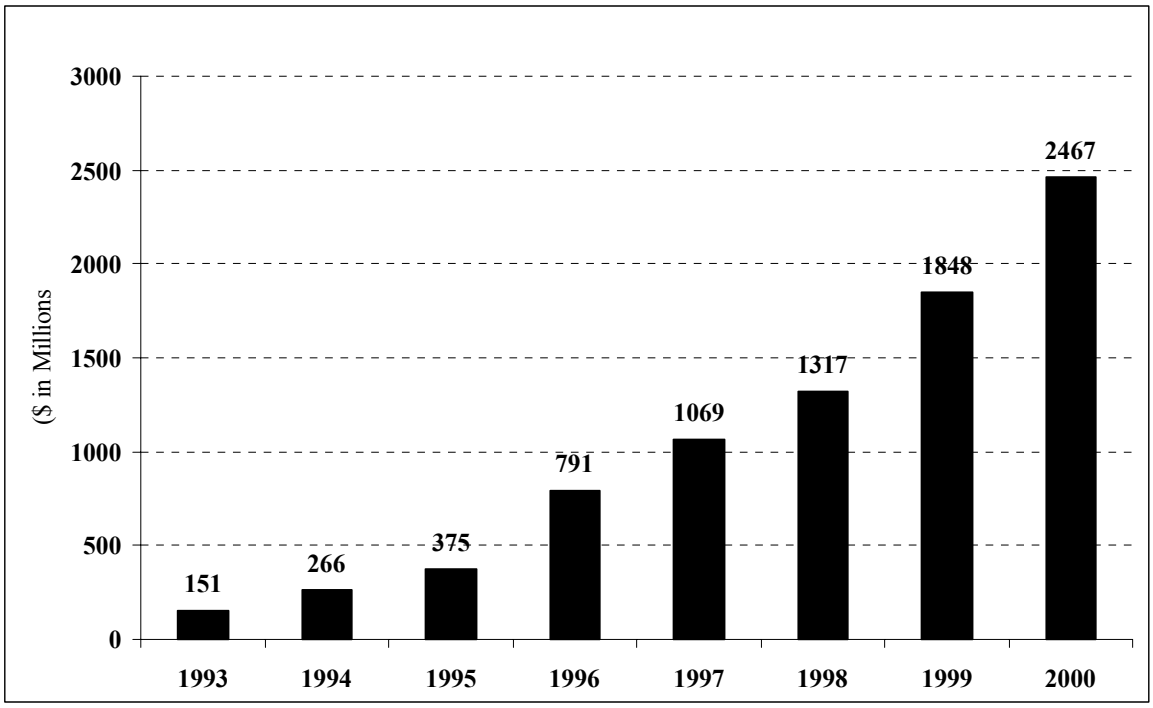


FIGURE 1
DTC PROMOTIONAL SPEND BY PHARMACEUTICAL COMPANIES

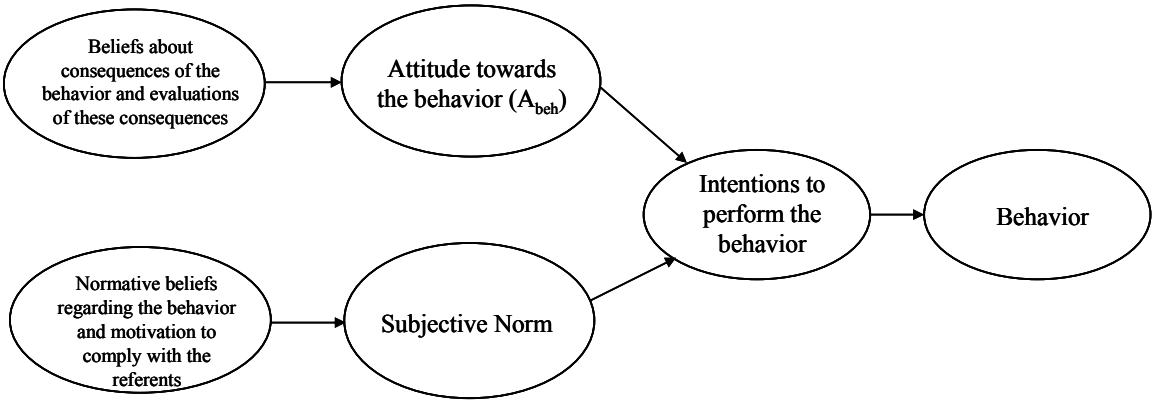
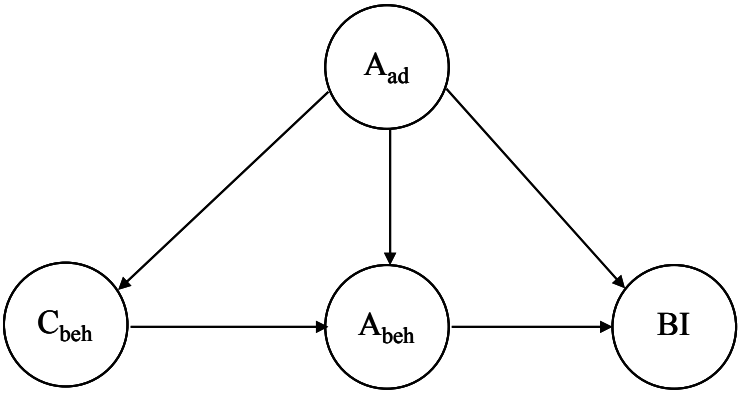
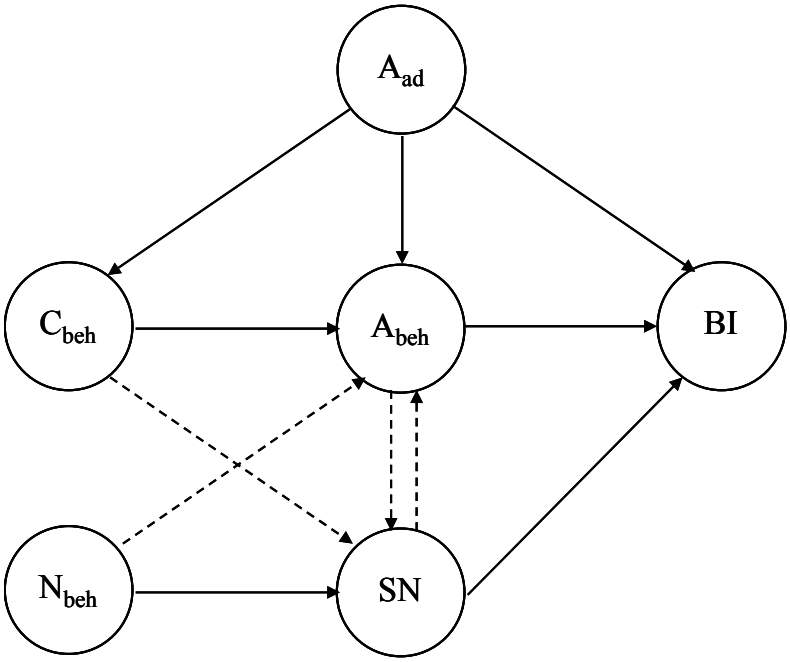


FIGURE 2
THE THEORY OF REASONED ACTION



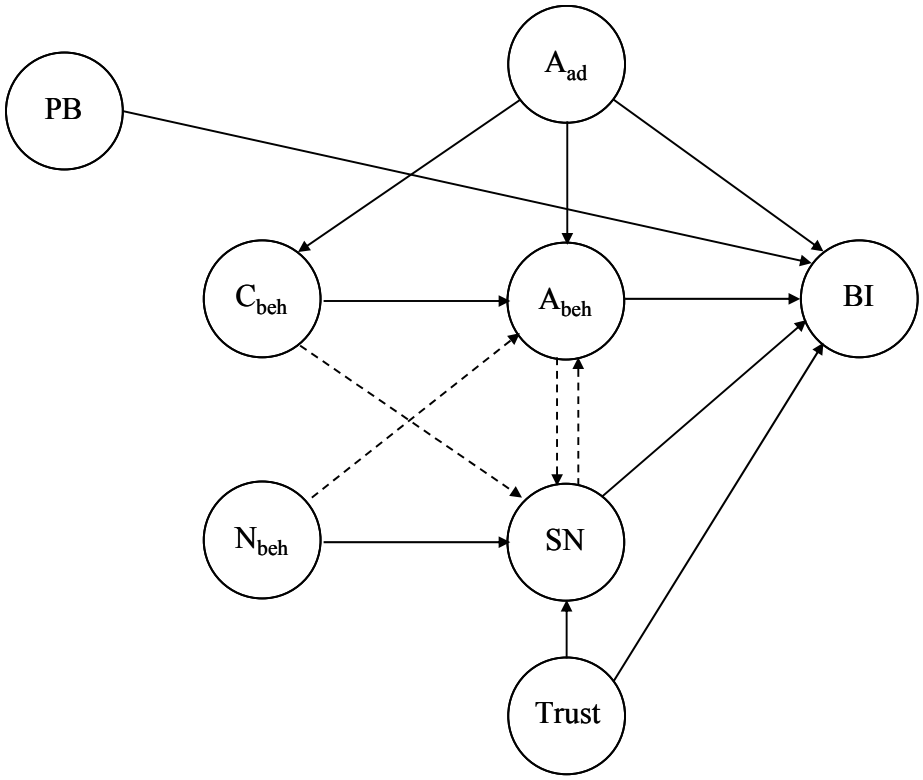
A_{ad} = Attitude towards DTC ad
C_{beh} = Cognitive structure of drug requesting behavior
A_{beh} = Attitude towards drug requesting behavior
BI = Intentions to request a drug

FIGURE 3
COGNITIVE AND AFFECTIVE CONSEQUENCES OF DTC ADS



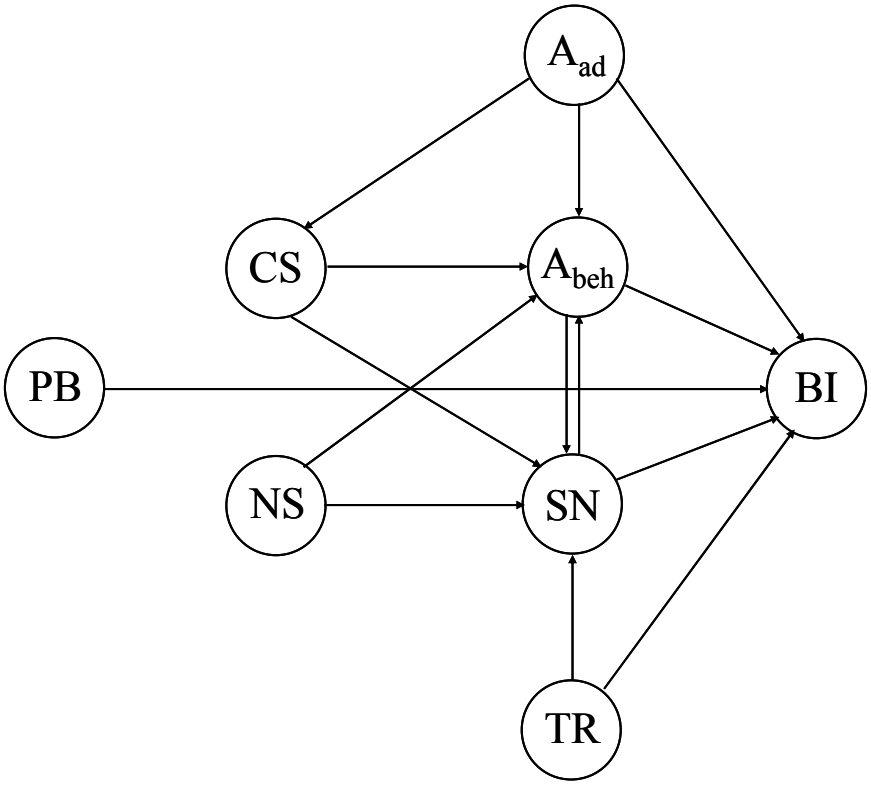
A_{ad} = Attitude towards DTC ad
C_{beh} = Cognitive structure of drug requesting behavior
A_{beh} = Attitude towards drug requesting behavior
N_{beh} = Normative structure of drug requesting behavior
SN = Subjective norms regarding drug requesting behavior
BI = Intentions to request a drug
- - → Indicates TRA model variants

FIGURE 4
A_{ad} AND THE THEORY OF REASONED ACTION



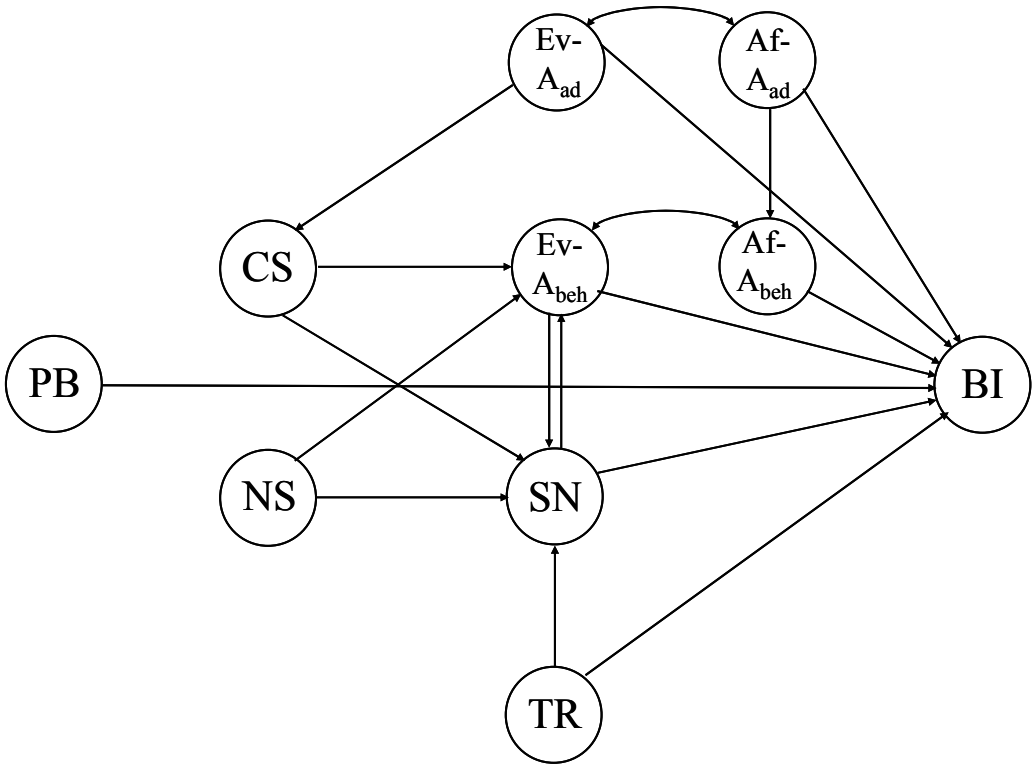
A_{ad} = Attitude towards DTC ad
C_{beh} = Cognitive structure of drug requesting behavior
A_{beh} = Attitude towards drug requesting behavior
N_{beh} = Normative structure of drug requesting behavior
SN = Subjective norms regarding drug requesting behavior
PB = Past behavior
Trust = Trust in physician
BI = Intentions to request a drug
- - - → Indicates TRA model variants

FIGURE 5
ANTECEDENTS OF DRUG REQUESTING BEHAVIOR



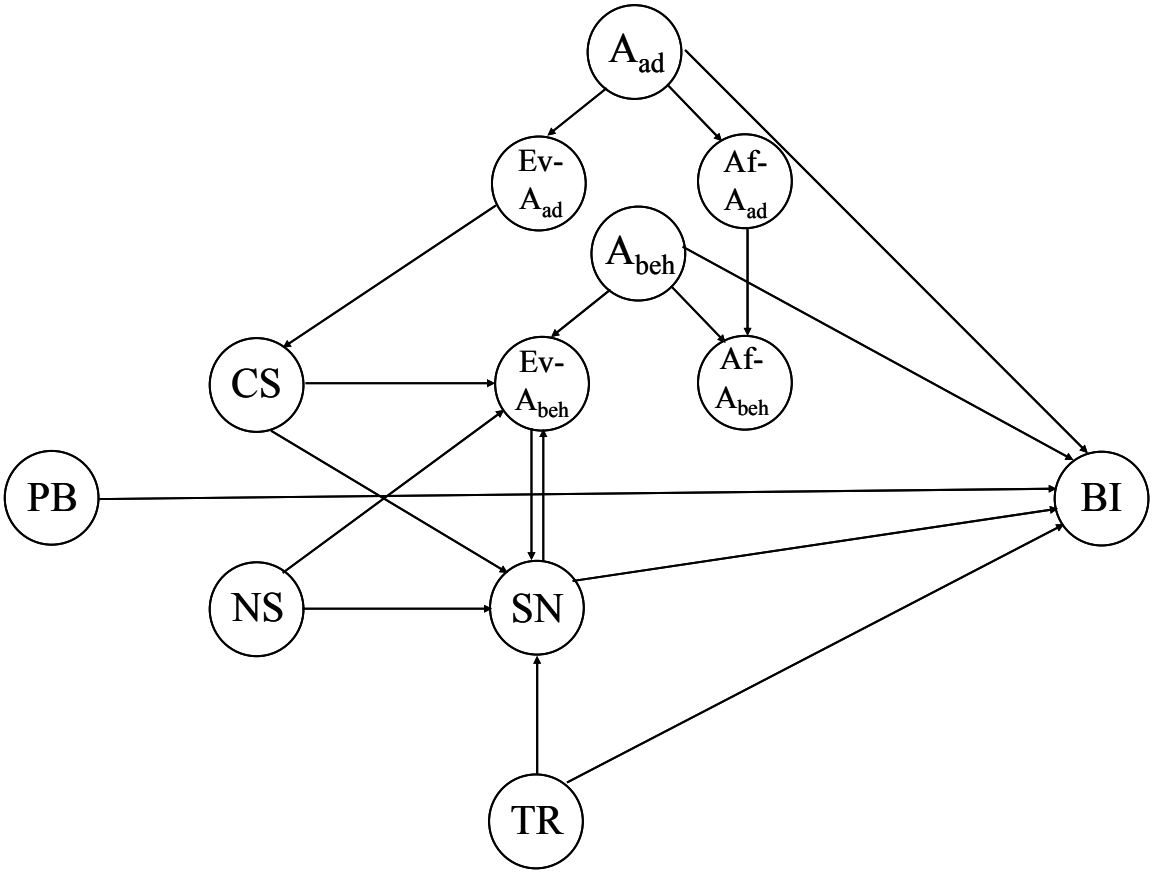
A_{ad} – Attitude towards DTC ad
A_{beh} – Attitude towards drug requesting behavior
SN – Subjective Norms towards drug requesting behavior
CS – Cognitive Structure
NS – Normative Structure
PB – Past Behavior
TR – Trust in Physician
BI – Behavioral Intentions

FIGURE 6
MODEL 1: ATTITUDE AS A UNIDIMENSIONAL FACTOR



Ev-A_{ad} – Evaluative attitude towards DTC ad
Af-Aad – Affective attitude towards DTC ad
Ev-A_{beh} – Evaluative attitude towards drug requesting behavior
Af-A_{beh} – Affective attitude towards drug requesting behavior
SN – Subjective Norms towards drug requesting behavior
CS – Cognitive Structure
NS – Normative Structure
PB – Past Behavior
TR – Trust in Physician
BI – Behavioral Intentions

FIGURE 7
MODEL 2: ATTITUDE AS TWO DISTINCT CORRELATED FACTORS



A_{ad} – Attitude towards DTC ad
Ev-A_{ad} – Evaluative attitude towards DTC ad
Af-Aad – Affective attitude towards DTC ad
A_{beh} – Attitude towards drug requesting behavior
Ev-A_{beh} – Evaluative attitude towards drug requesting behavior
Af-A_{beh} – Affective attitude towards drug requesting behavior
SN – Subjective Norms towards drug requesting behavior
CS – Cognitive Structure
NS – Normative Structure
PB – Past Behavior
TR – Trust in Physician
BI – Behavioral Intentions

FIGURE 8
MODEL 3: ATTITUDE AS A SECOND-ORDER FACTOR

APPENDIX B

TABLES

TABLE 1
FREQUENCY DISTRIBUTION OF ELICITED BELIEFS

	Beliefs	%
1.	Side Effects	26.1
2.	Does not pass through kidneys and liver	17.4
3.	Not absorbed in blood stream	13.0
4.	Lowers cholesterol	8.7
5.	Diet, exercise and drugs	4.3
6.	Does not require lots of water	4.3
7.	Gives more strength	4.3
8.	Help people think about their health	4.3
9.	Interaction with any food	4.3
10.	Life-style changes	4.3
11.	Makes you a healthier person	4.3
12.	Professional monitoring	4.3
	Total Beliefs Elicited	23

n=12

TABLE 2
FREQUENCY DISTRIBUTION OF ELICITED REFERENTS

	Referents	%
1.	Spouse / significant other	36.4
2.	Parents	27.3
3.	Friends	9.1
4.	Physician	9.1
5.	Family	4.5
6.	Manufacturer	4.5
7.	Naturalist	4.5
8.	Relatives	4.5
	Total Referents Elicited	22

n=12

TABLE 3
DEMOGRAPHICS

Characteristic	Category	
Gender	Male	41.2%
	Female	58.8%
Marital status	Married	76.4%
	Single, never married	4.3%
	Divorced	7.7%
	Separated	0.8%
	Widowed	8.9%
	Living with a partner	1.9%
Education	Less than high school	1.2%
	Completed some high school	5.5%
	High school graduate	23.5%
	Completed some college, but no degree	28.8%
	College graduate	16.0%
	Completed some graduate school but no degree	8.0%
	Completed graduate degree	13.9%
	Associate's degree	3.1%
Age	Mean (years)	62.2
	SD (years)	12.0
	Median (years)	63
	Min (years)	25
	Max (years)	88
Age Group	40 yrs or less	3.9%
	41 to 50 yrs	13.1%
	51 to 60 yrs	24.2%
	61 to 70 yrs	32.0%
	71 yrs or more	26.8%
Race	Caucasian	92.0%
	African American	2.7%
	Hispanic	1.2%
	Asian or Pacific Islander	0.4%
	Native American or Alaskan native	1.8%
	Mixed racial background	1.2%
	Other race	0.7%
Annual household income	Less than $15,000	8.1%
	$15,000 to $24,999	13.9%
	$25,000 to $34,999	15.3%
	$35,000 to $49,999	22.2%
	$50,000 to $74,999	20.8%
	$75,000 to $99,999	10.9%
	$100,000 or more	8.7%

n=744

TABLE 4
CORRELATION MATRIX OF INDIVIDUAL ITEMS

	BI1	BI2	BI3	Ev_Aad1	Ev_Aad2	Ev_Aad3	Ev_Aad4	Ev_Aad5	Af_Aad1	Af_Aad2	Af_Aad3	Af_Aad4	Af_Aad5
BI1	1.000												
BI2	0.913	1.000											
BI3	0.803	0.856	1.000										
Ev_Aad1	0.434	0.396	0.407	1.000									
Ev_Aad2	0.390	0.398	0.400	0.675	1.000								
Ev_Aad3	0.392	0.384	0.350	0.586	0.701	1.000							
Ev_Aad4	0.196	0.163	0.201	0.446	0.400	0.349	1.000						
Ev_Aad5	0.355	0.353	0.373	0.591	0.749	0.645	0.426	1.000					
Af_Aad1	0.445	0.430	0.367	0.464	0.438	0.466	0.317	0.443	1.000				
Af_Aad2	0.439	0.441	0.394	0.515	0.575	0.535	0.348	0.544	0.736	1.000			
Af_Aad3	0.423	0.439	0.392	0.489	0.518	0.501	0.336	0.487	0.689	0.819	1.000		
Af_Aad4	0.444	0.413	0.353	0.465	0.464	0.452	0.322	0.463	0.651	0.652	0.629	1.000	
Af_Aad5	0.457	0.468	0.420	0.514	0.552	0.530	0.343	0.565	0.672	0.769	0.711	0.662	1.000
Ev_Abeh1	0.605	0.581	0.559	0.469	0.392	0.398	0.295	0.380	0.551	0.546	0.524	0.539	0.588
Ev_Abeh2	0.514	0.484	0.447	0.407	0.407	0.402	0.260	0.413	0.465	0.562	0.545	0.506	0.587
Ev_Abeh3	0.608	0.591	0.562	0.478	0.440	0.428	0.285	0.438	0.471	0.525	0.508	0.496	0.551
Ev_Abeh4	0.625	0.606	0.592	0.482	0.418	0.407	0.307	0.418	0.495	0.520	0.497	0.475	0.533
Ev_Abeh5	0.498	0.488	0.454	0.444	0.454	0.480	0.269	0.452	0.518	0.563	0.566	0.521	0.604
Af_Abeh1	0.486	0.495	0.460	0.409	0.425	0.460	0.209	0.408	0.508	0.567	0.542	0.461	0.584
Af_Abeh2	0.566	0.547	0.528	0.440	0.440	0.422	0.294	0.415	0.465	0.503	0.461	0.467	0.541
Af_Abeh3	0.489	0.474	0.433	0.425	0.435	0.459	0.273	0.428	0.505	0.577	0.566	0.503	0.638
Af_Abeh4	0.561	0.552	0.519	0.484	0.465	0.437	0.307	0.449	0.521	0.559	0.534	0.537	0.586
Af_Abeh5	0.536	0.528	0.488	0.478	0.438	0.457	0.289	0.436	0.528	0.530	0.514	0.508	0.579
SN1	0.652	0.638	0.603	0.373	0.392	0.376	0.235	0.383	0.467	0.471	0.438	0.453	0.491
SN2	0.633	0.627	0.603	0.419	0.389	0.377	0.266	0.368	0.497	0.483	0.468	0.474	0.499
SN3	0.582	0.582	0.548	0.334	0.400	0.393	0.239	0.400	0.442	0.465	0.486	0.426	0.496
SN4	0.621	0.605	0.584	0.403	0.402	0.358	0.303	0.366	0.469	0.474	0.454	0.490	0.503

n=744

Legend: BI=Behavioral intentions; Ev_Aad=Evaluative attitude towards the ad; Af_Aad=Affective attitude towards the ad; Ev_Abeh=Evaluative attitude towards behavior; Af_Abeh=Affective attitude towards behavior; SN=Subjective norms; CS=Cognitive structure; NS=Normative structure; TR=Trust in physician; PB=Past behavior.

TABLE 4
CORRELATION MATRIX OF INDIVIDUAL ITEMS (continued)

	Ev_Abeh1	Ev_Abeh2	Ev_Abeh3	Ev_Abeh4	Ev_Abeh5	Af_Abeh1	Af_Abeh2	Af_Abeh3	Af_Abeh4	Af_Abeh5	SN1	SN2	SN3	SN4
BI1														
BI2														
BI3														
Ev_Aad1														
Ev_Aad2														
Ev_Aad3														
Ev_Aad4														
Ev_Aad5														
Af_Aad1														
Af_Aad2														
Af_Aad3														
Af_Aad4														
Af_Aad5														
Ev_Abeh1	1.000													
Ev_Abeh2	0.709	1.000												
Ev_Abeh3	0.695	0.591	1.000											
Ev_Abeh4	0.712	0.563	0.828	1.000										
Ev_Abeh5	0.690	0.724	0.645	0.632	1.000									
Af_Abeh1	0.647	0.663	0.627	0.565	0.768	1.000								
Af_Abeh2	0.635	0.536	0.743	0.752	0.584	0.543	1.000							
Af_Abeh3	0.637	0.710	0.597	0.561	0.738	0.687	0.613	1.000						
Af_Abeh4	0.663	0.596	0.779	0.760	0.640	0.608	0.757	0.638	1.000					
Af_Abeh5	0.642	0.577	0.708	0.678	0.652	0.610	0.697	0.699	0.753	1.000				
SN1	0.589	0.496	0.634	0.637	0.502	0.483	0.632	0.523	0.631	0.602	1.000			
SN2	0.631	0.511	0.717	0.717	0.553	0.561	0.677	0.539	0.677	0.622	0.819	1.000		
SN3	0.575	0.542	0.621	0.619	0.556	0.572	0.652	0.565	0.622	0.577	0.705	0.773	1.000	
SN4	0.615	0.511	0.692	0.706	0.541	0.549	0.723	0.530	0.682	0.608	0.769	0.881	0.794	1.000

n=744

Legend: BI=Behavioral intentions; Ev_Aad=Evaluative attitude towards the ad; Af_Aad=Affective attitude towards the ad; Ev_Abeh=Evaluative attitude towards behavior; Af_Abeh=Affective attitude towards behavior; SN=Subjective norms; CS=Cognitive structure; NS=Normative structure; TR=Trust in physician; PB=Past behavior.

TABLE 4
CORRELATION MATRIX OF INDIVIDUAL ITEMS (continued)

	BI1	BI2	BI3	Ev_Aad1	Ev_Aad2	Ev_Aad3	Ev_Aad4	Ev_Aad5	Af_Aad1	Af_Aad2	Af_Aad3	Af_Aad4	Af_Aad5
CS1	0.343	0.344	0.308	0.389	0.404	0.341	0.297	0.402	0.365	0.385	0.379	0.394	0.423
CS2	0.205	0.204	0.205	0.303	0.315	0.248	0.225	0.334	0.235	0.259	0.225	0.247	0.290
CS3	0.262	0.248	0.247	0.328	0.352	0.261	0.274	0.363	0.248	0.263	0.255	0.261	0.306
CS4	0.141	0.143	0.122	0.162	0.099	0.152	0.035	0.118	0.148	0.179	0.154	0.136	0.164
NS1	0.616	0.617	0.578	0.335	0.301	0.301	0.155	0.262	0.397	0.384	0.389	0.349	0.408
NS2	0.442	0.427	0.389	0.255	0.198	0.215	0.114	0.182	0.262	0.259	0.270	0.215	0.277
NS3	0.500	0.481	0.456	0.263	0.208	0.222	0.117	0.168	0.251	0.255	0.268	0.239	0.268
NS4	0.514	0.489	0.449	0.302	0.241	0.273	0.191	0.237	0.358	0.345	0.349	0.326	0.363
TR	-0.053	-0.063	-0.029	0.025	0.015	0.019	0.030	0.089	0.090	0.108	0.080	0.083	0.113
PB1	0.054	0.033	0.013	-0.006	0.012	-0.035	-0.002	0.055	0.035	0.013	-0.002	0.049	0.038
PB2	0.078	0.060	0.059	0.022	0.025	0.007	0.028	0.086	0.061	0.028	0.010	0.058	0.050
PB3	0.070	0.035	0.026	0.073	0.068	0.043	0.075	0.087	0.057	0.026	0.014	0.067	0.052

n=744

	Ev_Abeh1	Ev_Abeh2	Ev_Abeh3	Ev_Abeh4	Ev_Abeh5	Af_Abeh1	Af_Abeh2	Af_Abeh3	Af_Abeh4	Af_Abeh5	SN1	SN2	SN3	SN4
CS1	0.402	0.367	0.422	0.423	0.386	0.355	0.385	0.384	0.422	0.371	0.366	0.420	0.382	0.406
CS2	0.184	0.216	0.221	0.189	0.177	0.203	0.213	0.195	0.215	0.200	0.226	0.251	0.212	0.212
CS3	0.222	0.226	0.261	0.221	0.198	0.228	0.241	0.225	0.263	0.242	0.263	0.293	0.246	0.268
CS4	0.133	0.161	0.169	0.196	0.146	0.143	0.137	0.215	0.146	0.165	0.156	0.152	0.124	0.124
NS1	0.524	0.427	0.589	0.623	0.465	0.479	0.546	0.454	0.543	0.521	0.708	0.700	0.579	0.640
NS2	0.397	0.293	0.440	0.494	0.342	0.300	0.437	0.318	0.401	0.418	0.545	0.505	0.414	0.485
NS3	0.401	0.358	0.481	0.479	0.314	0.342	0.476	0.374	0.436	0.409	0.564	0.528	0.491	0.500
NS4	0.495	0.397	0.478	0.511	0.410	0.367	0.470	0.426	0.449	0.454	0.630	0.596	0.536	0.570
TR	0.066	0.058	0.004	0.029	0.066	0.083	0.007	0.028	0.019	0.013	-0.010	0.034	-0.025	0.021
PB1	0.025	-0.042	0.007	-0.022	-0.012	0.025	0.009	0.012	-0.028	-0.005	-0.011	-0.031	0.018	0.002
PB2	0.047	-0.003	0.025	-0.008	-0.022	0.044	0.017	0.014	-0.002	-0.001	0.004	0.006	0.030	0.042
PB3	0.082	0.028	0.024	0.016	0.019	0.062	0.021	0.031	0.044	0.034	0.015	0.025	0.039	0.089

n=744

Legend: BI=Behavioral intentions; Ev_Aad=Evaluative attitude towards the ad; Af_Aad=Affective attitude towards the ad; Ev_Abeh=Evaluative attitude towards behavior; Af_Abeh=Affective attitude towards behavior; SN=Subjective norms; CS=Cognitive structure; NS=Normative structure; TR=Trust in physician; PB=Past behavior.

TABLE 4
CORRELATION MATRIX OF INDIVIDUAL ITEMS (continued)

	CS1	CS2	CS3	CS4	NS1	NS2	NS3	NS4	TR	PB1	PB2	PB3
CS1	1.000											
CS2	0.511	1.000										
CS3	0.548	0.739	1.000									
CS4	0.146	0.059	0.039	1.000								
NS1	0.340	0.195	0.245	0.212	1.000							
NS2	0.182	0.102	0.095	0.099	0.676	1.000						
NS3	0.238	0.127	0.126	0.137	0.609	0.528	1.000					
NS4	0.281	0.136	0.168	0.175	0.683	0.610	0.659	1.000				
TR	0.065	0.126	0.099	-0.010	-0.009	0.001	-0.062	-0.009	1.000			
PB1	0.068	0.017	0.039	-0.074	-0.038	-0.020	-0.047	-0.023	0.141	1.000		
PB2	0.099	0.063	0.068	-0.097	-0.032	-0.011	-0.025	0.009	0.102	0.775	1.000	
PB3	0.042	0.018	0.047	-0.078	-0.001	-0.006	-0.027	-0.001	0.141	0.633	0.695	1.000

n=744

Legend: BI=Behavioral intentions; Ev_Aad=Evaluative attitude towards the ad; Af_Aad=Affective attitude towards the ad; Ev_Abeh=Evaluative attitude towards behavior; Af_Abeh=Affective attitude towards behavior; SN=Subjective norms; CS=Cognitive structure; NS=Normative structure; TR=Trust in physician; PB=Past behavior.

TABLE 5
CORRELATION MATRIX OF PARCELED ITEMS

	BI1	BI2	BI3	Ev_Aad1	Ev_Aad2	Af_Aad1	Af_Aad2	Ev_Abeh1	Ev_Abeh2	Af_Abeh1	Af_Abeh2	SN1	SN2
BI1	1.000												
BI2	0.913	1.000											
BI3	0.803	0.856	1.000										
Ev_Aad1	0.459	0.440	0.440	1.000									
Ev_Aad2	0.347	0.330	0.355	0.771	1.000								
Af_Aad1	0.501	0.499	0.441	0.656	0.569	1.000							
Af_Aad2	0.474	0.468	0.409	0.620	0.538	0.864	1.000						
Ev_Abeh1	0.632	0.615	0.586	0.564	0.481	0.643	0.594	1.000					
Ev_Abeh2	0.665	0.642	0.623	0.539	0.455	0.642	0.610	0.858	1.000				
Af_Abeh1	0.553	0.534	0.492	0.559	0.459	0.704	0.635	0.730	0.751	1.000			
Af_Abeh2	0.570	0.570	0.528	0.572	0.450	0.673	0.639	0.799	0.762	0.832	1.000		
SN1	0.677	0.661	0.631	0.467	0.419	0.569	0.537	0.772	0.734	0.608	0.665	1.000	
SN2	0.645	0.643	0.612	0.472	0.408	0.572	0.538	0.767	0.733	0.640	0.691	0.903	1.000
CS1	0.343	0.344	0.308	0.441	0.416	0.452	0.403	0.446	0.447	0.420	0.405	0.410	0.427
CS2	0.205	0.204	0.205	0.346	0.321	0.289	0.266	0.236	0.202	0.217	0.225	0.234	0.246
CS3	0.262	0.248	0.247	0.373	0.373	0.311	0.274	0.278	0.239	0.240	0.262	0.282	0.287
CS4	0.141	0.143	0.122	0.168	0.079	0.172	0.177	0.165	0.181	0.193	0.172	0.150	0.147
NS1	0.616	0.617	0.578	0.349	0.269	0.434	0.418	0.611	0.624	0.497	0.558	0.718	0.680
NS2	0.442	0.427	0.389	0.254	0.185	0.288	0.279	0.465	0.486	0.352	0.401	0.549	0.489
NS3	0.500	0.481	0.456	0.254	0.192	0.293	0.271	0.508	0.479	0.386	0.420	0.567	0.542
NS4	0.514	0.489	0.449	0.316	0.257	0.392	0.377	0.509	0.544	0.455	0.458	0.639	0.602
TR	-0.053	-0.063	-0.029	0.052	0.027	0.105	0.107	0.010	0.050	0.056	0.053	0.006	0.005
PB1	0.054	0.033	0.013	0.007	0.006	0.032	0.025	-0.003	-0.001	-0.015	0.011	-0.005	-0.007
PB2	0.078	0.060	0.059	0.046	0.032	0.045	0.047	0.015	0.018	-0.004	0.023	0.024	0.019
PB3	0.070	0.035	0.026	0.080	0.086	0.051	0.044	0.032	0.050	0.028	0.053	0.054	0.034

n=744

Legend: BI=Behavioral intentions; Ev_Aad=Evaluative attitude towards the ad; Af_Aad=Affective attitude towards the ad; Ev_Abeh=Evaluative attitude towards behavior; Af_Abeh=Affective attitude towards behavior; SN=Subjective norms; CS=Cognitive structure; NS=Normative structure; TR=Trust in physician; PB=Past behavior.

TABLE 5
CORRELATION MATRIX OF PARCELED ITEMS (continued)

	CS1	CS2	CS3	CS4	NS1	NS2	NS3	NS4	TR	PB1	PB2	PB3
BI1												
BI2												
BI3												
Ev_Aad1												
Ev_Aad2												
Af_Aad1												
Af_Aad2												
Ev_Abeh1												
Ev_Abeh2												
Af_Abeh1												
Af_Abeh2												
SN1												
SN2												
CS1	1.000											
CS2	0.511	1.000										
CS3	0.548	0.739	1.000									
CS4	0.146	0.059	0.039	1.000								
NS1	0.340	0.195	0.245	0.212	1.000							
NS2	0.182	0.102	0.095	0.099	0.676	1.000						
NS3	0.238	0.127	0.126	0.137	0.609	0.528	1.000					
NS4	0.281	0.136	0.168	0.175	0.683	0.610	0.659	1.000				
TR	0.065	0.126	0.099	-0.010	-0.009	0.001	-0.062	-0.009	1.000			
PB1	0.068	0.017	0.039	-0.074	-0.038	-0.020	-0.047	-0.023	0.141	1.000		
PB2	0.099	0.063	0.068	-0.097	-0.032	-0.011	-0.025	0.009	0.102	0.775	1.000	
PB3	0.042	0.018	0.047	-0.078	-0.001	-0.006	-0.027	-0.001	0.141	0.633	0.695	1.000

n=744

Legend: BI=Behavioral intentions; Ev_Aad=Evaluative attitude towards the ad; Af_Aad=Affective attitude towards the ad; Ev_Abeh=Evaluative attitude towards behavior; Af_Abeh=Affective attitude towards behavior; SN=Subjective norms; CS=Cognitive structure; NS=Normative structure; TR=Trust in physician; PB=Past behavior.

TABLE 6
SUMMARY STATICTICS OF INDIVIDUAL ITEMS

Item	Mean	SD	Skewness	Kurtosis
BI1	-0.90	1.932	0.454	-1.170
BI2	-0.76	1.951	0.327	-1.275
BI3	-0.36	1.916	0.043	-1.266
Ev_Aad1	0.87	1.473	-0.934	0.295
Ev_Aad2	0.92	1.392	-0.890	0.600
Ev_Aad3	0.46	1.208	-0.257	0.377
Ev_Aad4	1.20	1.487	-1.095	0.400
Ev_Aad5	0.95	1.394	-0.923	0.620
Af_Aad1	0.44	0.973	0.110	1.428
Af_Aad2	0.36	1.122	-0.182	1.210
Af_Aad3	0.52	1.055	0.043	1.202
Af_Aad4	0.23	1.065	-0.262	1.573
Af_Aad5	0.41	1.159	-0.213	1.146
Ev_Abeh1	0.30	1.128	-0.261	1.691
Ev_Abeh2	0.15	1.060	-0.234	1.979
Ev_Abeh3	0.35	1.470	-0.542	0.062
Ev_Abeh4	0.53	1.349	-0.597	0.637
Ev_Abeh5	0.26	1.115	-0.098	1.484
Af_Abeh1	0.23	1.244	-0.172	0.640
Af_Abeh2	0.32	1.463	-0.472	-0.007
Af_Abeh3	0.19	1.134	-0.266	1.586
Af_Abeh4	0.44	1.316	-0.488	0.706
Af_Abeh5	0.23	1.303	-0.456	0.690
SN1	-0.09	1.651	-0.191	-0.293
SN2	0.21	1.581	-0.360	-0.272
SN3	0.22	1.521	-0.293	-0.150
SN4	0.28	1.536	-0.425	-0.121
CS1	2.77	3.675	-0.469	0.573
CS2	3.61	3.686	-0.470	0.188
CS3	4.21	3.778	-0.704	0.479
CS4	-0.69	3.043	-0.307	0.952
NS1	-0.74	9.948	-0.094	0.269
NS2	-0.59	6.709	-0.216	3.412
NS3	-1.62	9.075	-0.370	0.836
NS4	-0.27	6.687	-0.101	2.802
TR	76.44	12.974	-0.523	0.396
PB1	3.51	1.230	-0.452	-0.714
PB2	3.53	1.127	-0.500	-0.364
PB3	3.75	1.107	-0.697	-0.142

Relative Multivariate Kurtosis = 1.401 n=744

Legend: BI=Behavioral intentions; Ev_Aad=Evaluative attitude towards the ad; Af_Aad=Affective attitude towards the ad; Ev_Abeh=Evaluative attitude towards behavior; Af_Abeh=Affective attitude towards behavior; SN=Subjective norms; CS=Cognitive structure; NS=Normative structure; TR=Trust in physician; PB=Past behavior.

TABLE 7
SUMMARY STATICTICS OF PARCELED ITEMS

Item	Mean	SD	Skewness	Kurtosis
BI1	-0.90	1.932	0.454	-1.170
BI2	-0.76	1.951	0.327	-1.275
BI3	-0.36	1.916	0.043	-1.266
Ev_Aad1	0.76	1.167	-0.828	1.040
Ev_Aad2	1.06	1.205	-0.821	0.751
Af_Aad1	0.39	0.965	0.010	1.578
Af_Aad2	0.40	0.977	0.054	1.224
Ev_Abeh1	0.37	1.298	-0.509	0.473
Ev_Abeh2	0.41	1.146	-0.439	1.174
Af_Abeh1	0.20	0.996	-0.122	1.993
Af_Abeh2	0.23	1.143	-0.330	0.970
SN1	0.10	1.499	-0.306	-0.118
SN2	0.21	1.460	-0.308	-0.010
CS1	2.77	3.675	-0.469	0.573
CS2	3.61	3.686	-0.470	0.188
CS3	4.21	3.778	-0.704	0.479
CS4	-0.69	3.043	-0.307	0.952
NS1	-0.74	9.948	-0.094	0.269
NS2	-0.59	6.709	-0.216	3.412
NS3	-1.62	9.075	-0.370	0.836
NS4	-0.27	6.687	-0.101	2.802
TR	76.44	12.974	-0.523	0.396
PB1	3.51	1.230	-0.452	-0.714
PB2	3.53	1.127	-0.500	-0.364
PB3	3.75	1.107	-0.697	-0.142

Relative Multivariate Kurtosis = 1.317 n=744

Legend: BI=Behavioral intentions; Ev_Aad=Evaluative attitude towards the ad; Af_Aad=Affective attitude towards the ad; Ev_Abeh=Evaluative attitude towards behavior; Af_Abeh=Affective attitude towards behavior; SN=Subjective norms; CS=Cognitive structure; NS=Normative structure; TR=Trust in physician; PB=Past behavior.

TABLE 8
RELIABILITY MEASURES OF SCALES WITH INDIVIDUAL ITEMS

Construct	Cronbach's alpha	Composite reliability	Variance Extracted
Behavioral Intentions	0.948	0.950	0.863
Evaluative_A_{ad}	0.859	0.871	0.582
Affective_A_{ad}	0.920	0.922	0.702
A_{ad}	---	0.847	0.734
Evaluative_A_{beh}	0.931	0.934	0.739
Affective_A_{beh}	0.912	0.916	0.686
A_{beh}	---	0.928	0.865
Subjective Norms	0.937	0.939	0.794
Cognitive Structure	0.818	0.829	0.621
Normative Structure	0.859	0.869	0.625
Past Behavior	0.875	0.879	0.708
Trust in Physician	0.862	---	---

n=744

TABLE 9
RELIABILITY MEASURES OF SCALES WITH PARCELED ITEMS

Construct	Cronbach's alpha	Composite reliability	Variance Extracted
Behavioral Intentions	0.948	0.950	0.863
Evaluative_A_{ad}	0.871	0.876	0.780
Affective_A_{ad}	0.927	0.928	0.865
A_{ad}	---	0.840	0.725
Evaluative_A_{beh}	0.920	0.922	0.855
Affective_A_{beh}	0.904	0.910	0.836
A_{beh}	---	0.950	0.905
Subjective Norms	0.949	0.948	0.900
Cognitive Structure	0.818	0.829	0.622
Normative Structure	0.859	0.869	0.626
Past Behavior	0.875	0.879	0.709
Trust in Physician	0.862	---	---

n=744

TABLE 10
FIT INDICES OF MEASUREMENT MODELS

Model	Attitude Structure	χ^2	*df*	RMSEA	CFI	TLI	SRMR
With Individual Items:							
1	One factor	3186.0#	638	0.085	0.97	0.97	0.056
2	Two distinct but correlated factors	1994.2#	621	0.055	0.99	0.98	0.050
3	2nd-order factor	2109.5#	634	0.057	0.99	0.98	0.054
With Parceled Items:							
1	One factor	1213.8#	225	0.077	0.97	0.97	0.056
2	Two distinct but correlated factors	609.3#	208	0.049	0.99	0.99	0.048
3	2nd-order factor	700.7#	221	0.052	0.99	0.98	0.051

# $p < 0.05$ n=744

Note.- RMSEA = Root Mean Square Error of Approximation; CFI = Comparative Fit Index; TLI = Tucker Lewis Index (or Nonnormed Fit Index); SRMR = Standardized Root Mean Square Residual.

TABLE 11
FACTOR LOADINGS OF MEASUREMENT MODEL

Construct with indicators below	Completely standardized	Unstandardized	Standard error	t-value
Behavioral Intentions				
BI1	0.94	1.00	---	---
BI2	0.97	1.05	0.02	56.32
BI3	0.87	0.92	0.02	39.84
A_{ad}				
Evaluative-A_{ad}	0.81	0.89	0.04	23.30
Affective-A_{ad}	0.89	0.83	0.03	27.08
Evaluative-A_{ad}				
Ev-Aad1	0.95	1.00	---	---
Ev-Aad2	0.81	0.89	0.03	25.71
Affective-A_{ad}				
Af-Aad1	0.96	1.00	---	---
Af-Aad2	0.90	0.95	0.02	38.60
A_{beh}				
Evaluative-A_{beh}	0.98	1.19	0.04	31.74
Affective-A_{beh}	0.92	0.82	0.03	26.73
Evaluative-A_{beh}				
Ev-Abeh1	0.93	1.00	---	---
Ev-Abeh2	0.92	0.87	0.02	43.67
Affective-A_{beh}				
Af-Abeh1	0.89	1.00	---	---
Af-Abeh2	0.94	1.21	0.03	37.86
Subjective Norm				
SN1	0.96	1.00	---	---
SN2	0.94	0.95	0.02	51.72
Cognitive Structure				
CS1	0.64	1.00	---	---
CS2	0.83	1.29	0.07	17.74
CS3	0.87	1.39	0.08	17.82
Normative Structure				
NS1	0.88	1.00	---	---
NS2	0.74	0.57	0.02	23.64
NS3	0.73	0.76	0.03	23.36
NS4	0.80	0.61	0.02	26.99
Past Behavior				
PB1	0.84	1.00	---	---
PB2	0.92	1.00	0.04	26.89
PB3	0.75	0.81	0.03	23.23
Trust in Physician				
TR	0.93	1.00	---	---

n=744

TABLE 12
FIT INDICES OF STURCTURAL MODELS

Model	Attitude Structure	χ^2	*df*	RMSEA	CFI	TLI	SRMR
1	One factor	1251.7#	233	0.077	0.97	0.97	0.060
2	Two distinct but correlated factors	1297.3#	229	0.079	0.97	0.96	0.240
3	2nd-order factor	663.5#	226	0.048	0.99	0.99	0.055

# $p < 0.05$ n=744

Note.- RMSEA = Root Mean Square Error of Approximation; CFI = Comparative Fit Index; TLI = Tucker Lewis Index (or Nonnormed Fit Index); SRMR = Standardized Root Mean Square Residual.

TABLE 13
PARAMETER ESTIMATES OF STRUCTURAL MODEL

Dependent variable with predictors below	Completely standardized	Unstandardized	Standard error	t-value
Behavioral Intentions (r^2=0.57)				
A_{ad}	0.07	0.12	0.11	1.10
A_{beh}	0.28#	0.51	0.15	3.50
Subjective norm	0.45#	0.57	0.07	8.03
Trust in Physician	-0.10#	-0.01	0.00	-3.35
Past behavior	0.06#	0.11	0.05	2.21
Evaluative-A_{ad} (r^2=0.64)				
A_{ad}	0.80#	0.87	0.04	22.20
Affective-A_{ad} (r^2=0.84)				
A_{ad}	0.92#	0.85	0.03	27.01
Cognitive structure (r^2=0.25)				
Evaluative-A_{ad}	0.50#	1.08	0.10	11.17
Evaluative-A_{beh} (r^2=0.97)##				
Cognitive structure	0.00	0.00	0.01	0.02
Subjective norm	0.06	0.05	0.05	1.04
Normative structure	0.04	0.01	0.01	0.77
A_{beh}	0.90#	1.09	0.07	16.17
Affective-A_{beh} (r^2=0.86)				
A_{beh}	0.76#	0.68	0.04	17.32
Affective-A_{ad}	0.22#	0.21	0.04	5.66
Subjective norm (r^2=0.81)				
Normative structure	0.43#	0.07	0.01	11.39
Evaluative-A_{beh}	0.50#	0.59	0.05	12.26
Cognitive structure	0.07#	0.05	0.01	3.22
Trust in Physician	-0.01	0.00	0.00	-0.38

# $p < 0.05$ n=744

The error variance was set to a small number 0.05 to resolve a Heywood case.

TABLE 14
COGNITIVE AND AFFECTIVE CONSEQUENCES OF A_{ad}
MULTIGROUP ANALYSIS

	Model	χ^2	*df*	RMSEA	CFI
1	All Paths Invariant	1185.0#	508	0.057	0.98
2	Cognitive Paths Invariant	1188.7#	511	0.057	0.98
3	Affective Paths Invariant	1185.3#	510	0.057	0.98

Model Comparison	$\Delta\chi^2$	Δdf	ΔRMSEA	ΔCFI
Model 1 vs. Model 2	3.7	3	0.000	0.00
Model 1 vs. Model 3	0.3	2	0.000	0.00

# $p < 0.05$ n=744

Note.- RMSEA = Root Mean Square Error of Approximation; CFI = Comparative Fit Index.

APPENDIX C

SURVEY MATERIALS

DTC AD of WELCHOL

If Healthy Food and Exercise aren't lowering your cholesterol enough,

add WelChol.® It is not absorbed in your bloodstream.

Lowers bad cholesterol an average of 15-18%

WelChol (colesevelam HCl) is a prescription drug that works with diet and exercise to lower LDL (bad) cholesterol an average of 15-18% (average effects depending on dose).

Doesn't pass through kidneys or liver

WelChol is different from many cholesterol drugs. It is nonsystemic, which means it isn't absorbed by your body–so it doesn't pass through your kidneys or liver.

Ask your doctor if WelChol is right for you

WelChol is not for everyone, especially those with bowel blockage. Tell your doctor if you have trouble swallowing or severe stomach or intestinal problems. Side effects may include constipation, indigestion and gas. **WelChol** has not been shown to prevent heart disease or heart attacks.

Call **1-866-WELCHOL** or visit **www.welchol.com**

NONsystemic

WelChol® TABLETS

(colesevelam HCl)

Helping you reach your cholesterol goal.

Please read additional information about WelChol on next page.

WELCHOL® (colesevelam hydrochloride) **TABLETS**
Rx only
Brief Summary—see package insert for full prescribing information.

INDICATIONS AND USAGE
WelChol®, administered alone or in combination with an HMG-CoA reductase inhibitor, is indicated as adjunctive therapy to diet and exercise for the reduction of elevated LDL cholesterol in patients with primary hypercholesterolemia (Fredrickson Type IIa).

CONTRAINDICATIONS
WelChol is contraindicated in individuals with bowel obstruction and in individuals who have shown hypersensitivity to any of the components of WelChol.

PRECAUTIONS
General: Patients with TG levels greater than 300 mg/dL were excluded from WelChol clinical trials. Caution should be exercised when treating patients with TG levels greater than 300 mg/dL.
In non-clinical safety studies, rats administered with colesevelam at doses greater than 30-fold the projected human clinical dose experienced hemorrhage from vitamin K deficiency. WelChol did not induce any clinically significant reduction in the absorption of vitamins A, D, E, or K during clinical trials of up to one year. However, caution should be exercised when treating patients with a susceptibility to vitamin K or fat soluble vitamin deficiencies.
The safety and efficacy of WelChol in patients with dysphagia, swallowing disorders, severe gastrointestinal motility disorders, or major gastrointestinal tract surgery have not been established. Consequently, caution should be exercised when WelChol is used in patients with these gastrointestinal disorders.
Information for the Patient: WelChol may be taken once per day with a meal, or taken twice per day in divided doses with meals. Patients should be directed to take WelChol with a liquid and a meal, and adhere to their NCEP-recommended diet. Patients should tell their physicians if they are pregnant, are intending to become pregnant, or are breast-feeding.
Laboratory Tests: Serum total-C, LDL-C, and TG levels should be determined periodically based on NCEP guidelines to confirm favorable initial and adequate long-term responses.
Drug Interactions: WelChol has been studied in several human drug interaction studies in which it was administered with a meal and the test drug. WelChol was found to have no significant effect on the bioavailability of digoxin, lovastatin, metoprolol, quinidine, valproic acid, and warfarin. WelChol decreased the C_{max} and AUC of sustained-release verapamil by approximately 31% and 11%, respectively. Since there is a high degree of variability in the bioavailability of verapamil, the clinical significance of this finding is unclear. In clinical studies, co-administration of WelChol with atorvastatin, lovastatin, or simvastatin did not interfere with the lipid-lowering activity of the HMG-CoA reductase inhibitor. Other drugs have not been studied. When administering other drugs for which alterations in blood levels could have a clinically significant effect on safety or efficacy, physicians should consider monitoring drug levels or effects.
Carcinogenesis, Mutagenesis, Impairment of Fertility
A 104-week carcinogenicity study with colesevelam (WelChol) was conducted in CD-1 mice, at oral dietary doses up to 3 g/kg/day. This dose was approximately 50 times the maximum recommended human dose of 4.5 g/day, based on body weight, mg/kg. There were no significant drug-induced tumor findings in male or female mice. In a 104-week carcinogenicity study with colesevelam (WelChol) in Harlan Sprague-Dawley rats, a statistically significant increase in the incidence of pancreatic acinar cell adenoma was seen in male rats at doses >1.2 g/kg/day (approximately 20 times the maximum human dose, based on body weight, mg/kg) (trend test only). A statistically significant increase in thyroid C-cell adenoma was seen in female rats at 2.4 g/kg/day (approximately 40 times the maximum human dose, based on body weight, mg/kg).
Colesevelam and four degradants present in the drug substance have been evaluated for mutagenicity in the Ames test and a mammalian chromosomal aberration test. The four degradants and an extract of the parent compound did not exhibit genetic toxicity in an *in vitro* bacterial mutagenesis assay in *S. typhimurium* and *E. coli* (Ames assay) with or without rat liver metabolic activation. An extract of the parent compound was positive in the Chinese Hamster Ovary (CHO) cell chromosomal aberration assay in the presence of metabolic activation and negative in the absence of metabolic activation. The results of the CHO cell chromosomal aberration assay with two of the four degradants, decylamine HCl and aminohexyltrimethyl ammonium chloride HCl, were equivocal in the absence of metabolic activation and negative in the presence of metabolic activation. The other two degradants, didecylamine HCl and 6-decylaminohexyltrimethyl ammonium chloride HCl, were negative in the presence and absence of metabolic activation.
Colesevelam did not impair fertility in rats at doses of up to 3 g/kg/day (approximately 50 times the maximum human dose, based on body weight, mg/kg).

Pregnancy Category B: Reproduction studies have been performed in rats and rabbits at doses up to 3 g/kg/day and 1 g/kg/day, respectively (approximately 50 and 17 times the maximum human dose, based on body weight, mg/kg), and have revealed no evidence of harm to the fetus due to colesevelam. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed. Requirements for vitamins and other nutrients are increased in pregnancy. The effect of WelChol on the absorption of vitamins has not been studied in pregnant women.
Pediatric Use: The safety and efficacy of colesevelam (WelChol) have not been established in pediatric patients.
Geriatric Use: There is no evidence for special considerations when colesevelam (WelChol) is administered to elderly patients.

ADVERSE REACTIONS
WelChol treatment-emergent adverse events that occurred in greater than 2% of patients in an integrated safety analysis are presented in the table below.

Frequent (>2%) Treatment-Emergent Adverse Events By Treatment Category

BODY SYSTEM/ ADVERSE EVENT	Placebo (N=258) %	WELCHOL ONLY (N=807) %
Body as a Whole		
Infection	13	10
Headache	8	6
Pain	7	5
Back Pain	6	3
Abdominal Pain	5	5
Flu Syndrome	3	3
Accidental Injury	3	4
Asthenia	2	4
Digestive System		
Flatulence	14	12
Constipation	7	11
Diarrhea	7	5
Nausea	4	4
Dyspepsia	3	8
Respiratory System		
Sinusitis	4	2
Rhinitis	3	3
Cough Increased	2	2
Pharyngitis	2	3
Musculoskeletal System		
Myalgia	0	2

OVERDOSAGE
Because WelChol is not absorbed, the risk of systemic toxicity is low. Doses in excess of 4.5 g per day have not been tested.

DOSAGE AND ADMINISTRATION
Monotherapy: The recommended starting dose of WelChol is 3 tablets taken twice per day with meals or 6 tablets once per day with a meal. The WelChol dose can be increased to 7 tablets, depending upon the desired therapeutic effect. WelChol should be taken with a liquid.
Combination Therapy: WelChol, at doses of 4 to 6 tablets per day, has been shown to be safe and effective when dosed at the same time (i.e., co-administered) as an HMG-CoA reductase inhibitor or when the two drugs are dosed apart. WelChol should be taken with a liquid. For maximal therapeutic effect in combination with an HMG-CoA reductase inhibitor, the recommended dose of WelChol is 3 tablets taken twice per day with meals or 6 tablets taken once per day with a meal.

HOW SUPPLIED:
WelChol is supplied as an off-white, film-coated solid tablet imprinted with the word "Sankyo" over "C01," containing 625 mg colesevelam, magnesium stearate, microcrystalline cellulose, silicon dioxide, HPMC (hydroxypropyl methylcellulose), and acetylated monoglyceride.

Revised 03/02
Manufactured for: Sankyo Pharma Inc. New York, NY 10017
Licensed from: Geltex Pharmaceuticals, Inc.
by: Patheon YM Inc. Toronto, Ontario M3B 1Y5

WelChol® TABLETS
(colesevelam HCl)

Please visit our Web site at www.welchol.com

SANKYO

SPWC00-0011

ELICITATION STUDY

Recruitment E-mail Text

Hello College of Pharmacy Employee:

I need 10 to 15 people to participate in a brief and interesting survey. These people should have high cholesterol or think they might have high cholesterol in the future. If this sounds like you, I would appreciate your participation in the study.

The research concerns opinions regarding a colorful advertisement of a cholesterol-reducing drug. Most people find these survey's very enjoyable. This study is an ongoing research for my Ph.D. degree. The study will take approximately 10 to 15 minutes.

If you are interested please reply to this email and I will be glad to stop by your office at a time convenient to you.

Thank you for your interest.

Regards,
Shashank

Shashank B.Shinde
Ph.D. student
Room # 268, CAP dept, College of Pharmacy,
The University of Georgia, Athens, GA 30605
Ph: 706-542-5311
e-mail: shindes@rx.uga.edu

ELICITATION STUDY

Consent Form

Drug Requesting Behavior Consent Form

I, _____ agree to take part in the research titled "ANTECEDENTS OF DRUG REQUESTING BEHAVIOR" conducted by Shashank B. Shinde from the Clinical and Administrative Pharmacy Department at the College of Pharmacy, University of Georgia (Ph: 706-542-5311) under the direction of Dr. Matthew Perri III, (Professor, CAP dept, College of Pharmacy, 706-542-5365). I understand that I do not have to take part if I do not want to. I can stop taking part without giving any reason, and without penalty. I can ask to have all of the information about me returned to me, removed from the research records, or destroyed.

The reason for the study is to examine the issues consumers evaluate after watching an advertisement of a medical drug.

I will not benefit directly from this research. However, my participation in this research will help the researcher to develop specific questions for future research.

If I volunteer to take part in this study, I will be asked to do the following things:
1) Watch a print advertisement of a cholesterol-lowering drug WELCHOL® for about 3 minutes.
2) Answer questions pertaining to the advertised product WELCHOL® which will take 15 minutes.

No discomfort, stress or risks are foreseen as a result of taking this survey.

The results of my participation will be kept confidential. The only person who will know that I am a research subject is the researcher. No information about me, or provided by me during the research, will be shared with others without my written permission, except if it is necessary to protect my rights or welfare; or if required by law.

The investigators will answer any further questions about the research, now or during the course of the project, and can be reached by telephone at: 706-542-5311.

My signature below indicates that the researcher has answered all of my questions to my satisfaction and that I consent to volunteer for this study. I have been given a copy of this form.

_____ _____

Signature of Researcher, Date Signature of Participant, Date

Phone #: 706-542-5311
e-mail: shindes@rx.uga.edu

For questions or problems about your rights please call or write: Chris A. Joseph, Ph.D., Human Subjects Office, University of Georgia, 606A Boyd Graduate Studies Research Center, Athens, Georgia 30602-7411; Telephone: 706-542-3199; e-mail address: IRB@uga.edu

ELICITATION STUDY

Questionnaire

Antecedents of Drug Requesting Behavior Survey

Directions: Please answer the following questions about yourself. You can check mark the appropriate box.

1) Are you over 18 years of age?

☐ Yes

☐ No

2) What is your gender?

☐ Male

☐ Female

3) Do you have high-cholesterol?

☐ Yes

☐ No

If No, do you consider yourself to be at risk of having high-cholesterol in the future?

☐ Yes

☐ No (Thank you, those were all the questions)

On the next page there is an advertisement of a cholesterol lowering drug WELCHOL®. Please take a moment to observe the advertisement and answer the following questions. You may refer to the advertisement again while answering the questions.

Remember, your survey responses will remain confidential and will never be reported individually.

In the space provided please answer the following questions. There is no right or wrong answer. Don't worry about grammar, spelling or punctuations, but please write legibly.

1) What do you think are the advantages of requesting WelChol® from your physician?

2) What do you think are the disadvantages of requesting WelChol® from your physician?

3) Is there anything else you associate with requesting WelChol® from your physician?

4) Are there any individuals or groups who would approve of your requesting WelChol® from your physician?

5) Are there any individuals or groups who would disapprove of your requesting WelChol® from your physician?

6) Are there any other individuals or groups who come to mind when you think about requesting WelChol® from your physician?

That's all the questions. Thanks a lot for your help !

MAIN STUDY

Advance Notice Post Card

Dear Health Care Consumer,

I am a Ph.D. student at the College of Pharmacy, The University of Georgia. In a few days you will receive a survey in the mail concerning your opinions on a prescription drug advertisement. This study is entitled 'Antecedents of drug requesting behavior' and is being conducted to better understand the effects of prescription drug advertising.

Your responses are very valuable to us. When you receive the survey please take a few moments to complete the questionnaire. Should you have any questions about this study please feel free to call me at 706-542-5311 or my professor Dr.Matthew Perri III at 706-542-5365.

Please watch out for the interesting survey in your mail over the next few days!

Thank you.
Sincerely,

Shashank B. Shinde
Ph.D. student
Ph: 706-542-5311
e-mail: shindes@rx.uga.edu

Matthew Perri III, R.Ph., Ph.D.
Professor and Assoc, Head
Ph: 706-542-5365
e-mail: mperri@rx.uga.edu

MAIN STUDY

Questionnaire

The University of Georgia

College of Pharmacy

February 4, 2003

Dear Health Care Consumer,

A few days back I mailed you an invitation to participate in an interesting research study. I am enclosing the survey materials in this letter. You can help in my research effort by completing this survey. This study is entitled 'Antecedents of drug requesting behavior' and is being conducted to better understand the effects of prescription drug advertising in print media. The results of this research will help us understand how consumers process the technical/medical information in an advertisement. These results will be helpful to better design advertising campaigns in order to effectively communicate information about prescription drugs.

This survey is anonymous. All results will be presented as group data. Participation in the study is voluntary. No discomfort, stress or risks are foreseen as a result of taking this survey.

The approximate time to complete the survey is about 15 minutes. If you decide to take part in this study, you will be asked to do the following things:

1) Review a print advertisement of a cholesterol-lowering drug Welchol® for about 3 minutes.
2) Answer questions pertaining to the advertised product Welchol® for about 12 minutes.

Please help us maximize our response rate and take just a few moments to complete this questionnaire today. After you complete the survey, simply fold and staple or tape it with the return mail address showing. If you wish not to participate in the study please destroy the survey materials. Should you have any questions about this study please feel free to call me at 706-542-5311 or my professor Dr.Matthew Perri III at 706-542-5365.

Thank you very much for your participation.

Sincerely,

Shashank B. Shinde
Ph.D. student
Ph: 706-542-5311
e-mail: shindes@rx.uga.edu

Matthew Perri III, R.Ph., Ph.D.
Professor and Asso. Head
Ph: 706-542-5365
e-mail: mperri@rx.uga.edu

Department of Clinical and Administrative Pharmacy • Athens, Georgia 30602-2354 • Telephone (706) 542-7400 • Fax (706) 542-5228

DRUG REQUESTING BEHAVIOR SURVEY

Part A:

Please look at the advertisement of a cholesterol reducing prescription drug – Welchol®. Observe the advertisement for a moment as you would normally do and please answer the following questions.

Part B: Survey Questionnaire

Instructions: ***Please answer the following questions by placing an 'X' in the appropriate blank. For example, if you think the weather today is extremely good, then you would place your mark as follows:***

Good	_____	_____	_____	_____	_____	_____	_____	Bad
	extremely	*quite*	*slightly*	*neither*	*slightly*	*quite*	*extremely*	

Please place your marks in the middle of the spaces, not on the boundaries:

Good	_____	X	_____	_____	_____	X	_____	Bad
		this				*not this*		

Be sure to answer all items – please do not omit any.
Never put more than one check mark on a single scale.

Section 1: **Prescription Requesting Intentions**

My intention to request WelChol® from my physician during the next visit is

Likely	_____	_____	_____	_____	_____	_____	_____	Unlikely
	extremely	quite	slightly	neither	slightly	quite	extremely	
Probable	_____	_____	_____	_____	_____	_____	_____	Improbable
Possible	_____	_____	_____	_____	_____	_____	_____	Impossible

Section 2: **Now please think only about the advertisement of WelChol®.**

The ad of WelChol® is

Persuasive	_____	_____	_____	_____	_____	_____	_____	Unpersuasive
	extremely	quite	slightly	neither	slightly	quite	extremely	
Worthless	_____	_____	_____	_____	_____	_____	_____	Valuable
Imperfect	_____	_____	_____	_____	_____	_____	_____	Perfect
Informative	_____	_____	_____	_____	_____	_____	_____	Uninformative
Useless	_____	_____	_____	_____	_____	_____	_____	Useful

The ad of WelChol® makes me feel

Delighted	extremely	quite	slightly	neither	slightly	quite	extremely	Sad
Annoyed								Happy
Unpleasant								Pleasant
Excited								Bored
Unsatisfied								Satisfied

<u>Section 3:</u> Please think about the next appointment with your physician.

For me, requesting WelChol® from my physician during the next visit can be described as

Rewarding	extremely	quite	slightly	neither	slightly	quite	extremely	Punishing
Unenjoyable								Enjoyable
Wise								Foolish
Beneficial								Harmful
Unpleasant								Pleasant
Uncomfortable								Comfortable
Useful								Useless
Unattractive								Attractive
Good								Bad
Appealing								Unappealing

Most people who are important to me think I

should		should not

request WelChol® from my physician

Most people who are important to me probably consider my requesting WelChol® from my physician to be

Wise	extremely	quite	slightly	neither	slightly	quite	extremely	Foolish
Useless								Useful
Valuable								Worthless

Section 4: We would like to have your opinions on drugs used for cholesterol management

By requesting Welchol® from my physician, I will get a prescription drug that can lower my cholesterol by 15-18%.

Likely _____:_____:_____:_____:_____:_____:_____ Unlikely
extremely quite slightly neither slightly quite extremely

By requesting Welchol® from my physician, I will get a prescription drug that will not be absorbed in the bloodstream.

Likely _____:_____:_____:_____:_____:_____:_____ Unlikely
extremely quite slightly neither slightly quite extremely

By requesting Welchol® from my physician, I will get a prescription drug that does not pass through kidneys or liver.

Likely _____:_____:_____:_____:_____:_____:_____ Unlikely
extremely quite slightly neither slightly quite extremely

By requesting Welchol® from my physician, I will get a prescription drug that has some side effects.

Likely _____:_____:_____:_____:_____:_____:_____ Unlikely
extremely quite slightly neither slightly quite extremely

Lowering cholesterol by 15-18% is

Good _____:_____:_____:_____:_____:_____:_____ Bad
extremely quite slightly neither slightly quite extremely

A drug that is not absorbed in the bloodstream is

Good _____:_____:_____:_____:_____:_____:_____ Bad
extremely quite slightly neither slightly quite extremely

A drug that does not pass through kidneys or liver is

Good _____:_____:_____:_____:_____:_____:_____ Bad
extremely quite slightly neither slightly quite extremely

A drug that has some side effects is

Good _____:_____:_____:_____:_____:_____:_____ Bad
extremely quite slightly neither slightly quite extremely

Section 5: Now we would like to know how you think other people would like you to request Welchol® from your physician.

My spouse/partner thinks that I

Should _____:_____:_____:_____:_____:_____:_____ should not
request WelChol® from my physician

My parents think that I

Should _____:_____:_____:_____:_____:_____:_____ should not
request WelChol® from my physician

My physician thinks that I

Should _____:_____:_____:_____:_____:_____:_____ should not
request WelChol® from him

My friends/coworkers think that I

Should _____:_____:_____:_____:_____:_____:_____ should not
request WelChol® from my physician

Generally speaking, how much do you want to do what your spouse/partner thinks you should do?

Not at all _____:_____:_____:_____:_____:_____:_____ Very much

Generally speaking, how much do you want to do what your parents think you should do?

Not at all _____:_____:_____:_____:_____:_____:_____ Very much

Generally speaking, how much do you want to do what your physician thinks you should do?

Not at all _____:_____:_____:_____:_____:_____:_____ Very much

Generally speaking, how much do you want to do what your friends/co-workers thinks you should do?

Not at all _____:_____:_____:_____:_____:_____:_____ Very much

Section 6: **The purpose of this section is to measure your involvement or interest in 'cholesterol management'. To take this measure, we need you to judge cholesterol management against a series of descriptive scales according to how you perceive cholesterol management.**

To me cholesterol management is

Important	_____	_____	_____	_____	_____	_____	_____	Unimportant
	extremely	quite	slightly	neither	slightly	quite	extremely	
Boring	_____	_____	_____	_____	_____	_____	_____	Interesting
Relevant	_____	_____	_____	_____	_____	_____	_____	Irrelevant
Exciting	_____	_____	_____	_____	_____	_____	_____	Unexciting
Means nothing	_____	_____	_____	_____	_____	_____	_____	Means a lot
Appealing	_____	_____	_____	_____	_____	_____	_____	Unappealing
Fascinating	_____	_____	_____	_____	_____	_____	_____	Mundane
Worthless	_____	_____	_____	_____	_____	_____	_____	Valuable
Involving	_____	_____	_____	_____	_____	_____	_____	Uninvolving
Not needed	_____	_____	_____	_____	_____	_____	_____	Needed

Section 7: **Please indicate how often you have asked your physician about the following issues in your earlier visits.**

		always	often	occasionally	seldom	never
a.	Information about a newly diagnosed medical condition	_____	_____	_____	_____	_____
b.	Different treatment options available	_____	_____	_____	_____	_____
c.	Drug prescribed by the physician	_____	_____	_____	_____	_____

Section 8: **About your Physician**

Please respond to the following statements by circling a number from 1 to 5 according to these directions:

1 = Strongly disagree
2 = Disagree
3 = neither Agree nor Disagree
4 = Agree
5 = Strongly Agree

		Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
a.	I doubt that my doctor really cares about me as a person.	1	2	3	4	5
b.	My doctor is usually considerate of my needs and puts them first.	1	2	3	4	5
c.	I trust my doctor so much I always try to follow his/her advice.	1	2	3	4	5
d.	If my doctor tells me something is so, then it must be true.	1	2	3	4	5
e.	I sometimes distrust my doctor's opinion and would like a second one.	1	2	3	4	5
f.	I trust my doctor's judgments about my medical care.	1	2	3	4	5
g.	I feel my doctor does not do everything he/she should about my medical care.	1	2	3	4	5
h.	I trust my doctor to put my medical needs above all other considerations when treating my medical problems.	1	2	3	4	5
i.	My doctor is well qualified to manage (diagnose and treat or make an appropriate referral) medical problems like mine.	1	2	3	4	5
j.	I trust my doctor to tell me if a mistake was made about my treatment.	1	2	3	4	5
k.	I sometimes worry that my doctor may not keep the information we discuss totally private.	1	2	3	4	5

Section 9: Finally, just a few questions about you

What is your gender?

- ❑ Male
- ❑ Female

What is your marital status?

- ❑ Married
- ❑ Single, never married
- ❑ Divorced
- ❑ Separated
- ❑ Widowed
- ❑ Living with a partner

What is your highest level of education?

- ❑ Less than high school
- ❑ Completed some high school
- ❑ High school graduate or equivalent (e.g., GED)
- ❑ Completed some college, but no degree
- ❑ College graduate (e.g., B.A., A.B., B.S.)
- ❑ Completed some graduate school but no degree
- ❑ Completed graduate degree (e.g., M.S., M.B.A., Ph.D.)
- ❑ Associate's degree

What is your year of birth?
(Please enter as a four-digit number, e.g., 1963)

_____

Do you consider yourself . . .?

- ❑ Caucasian
- ❑ African American
- ❑ Hispanic
- ❑ Asian or Pacific Islander
- ❑ Native American or Alaskan native
- ❑ Mixed racial background
- ❑ Other race

What is your annual household income?

- ❑ Less than $15,000
- ❑ $15,000 to $24,999
- ❑ $25,000 to $34,999
- ❑ $35,000 to $49,999
- ❑ $50,000 to $74,999
- ❑ $75,000 to $99,999
- ❑ $100,000 or more

Did you hear or see the advertisement of Welchol® before?

- ❑ Yes
- ❑ No

How satisfied are you with your current cholesterol treatment?

- ❑ Very satisfied
- ❑ Somewhat satisfied
- ❑ Neither satisfied nor dissatisfied
- ❑ Somewhat dissatisfied
- ❑ Very dissatisfied
- ❑ I am not taking any treatment for high cholesterol

That's all the questions. Thanks a lot of your help!
Please fold the survey and staple or tape it with the return mail address showing.