RISK COMMUNICATION IN PRESCRIPTION DRUG ADVERTISEMENTS: AN INVESTIGATION OF CONSUMERS' INFORMATION PROCESSING FROM THE "BRIEF SUMMARY" IN PRINT DIRECT-TO-CONSUMER ADS

by

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(Under the Direction of Matthew Perri III)

ABSTRACT

The "brief summary" in print prescription drug (DTC) ads is under scrutiny because of a general consensus that it does not adequately facilitate consumers' understanding of drug risks and side effects. Recently, the FDA has recommended that drug marketers use more patient friendly brief summary formats in DTC ads. However, there is little empirical evidence regarding the comparative influence of different formats on consumers' drug-related knowledge, and their perceptions and responses to DTC ads.

This study involved a series of qualitative focus group interviews that elicited consumer opinions on design preferences for the brief summary in print DTC ads. Subsequently, we conducted a mall intercept survey with 307 consumers, using a monadic experimental design, to assess the comparative effectiveness of the different formats in influencing outcomes related to consumer information processing.

The results reported here show that consumers' knowledge of drug risks and side effects was higher when a newer format was used vs. the existing fine-print format. Overall, information processing improved when a brief summary was present, underscoring the necessity of this information. Regardless of whether new or existing brief summary formats were used, consumers tended to learn the benefits of a drug better than its risks. Greater knowledge of the risks and side effects led to favorable brand attitudes and did not increase the perceived risk associated with the product. Clearly, marketers should not be hesitant to incorporate risk information in DTC ads for fear of discouraging trial and adoption. Newer brief summary formats should be used since they tend to facilitate effective information processing more than the existing fine print format.

INDEX WORDS: Risk Communication, Brief summary, DTC Advertising, Information processing, FDA Guidance

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DEDICATION

To Aai and Baba and Manasi. Your blessings, love and encouragement have transcended the geographical boundaries that separate us and guided me to realize the potential that lies within.

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TABLE OF CONTENTS

Page

LIST OF TABLES

Page

LIST OF FIGURES

Page

CHAPTER 1

INTRODUCTION

1.1 Introduction

Warnings in product advertisements are designed to alert consumers to the potential hazardous effects associated with product use. In turn, it is anticipated that this may deter harmful behaviors or induce a positive behavioral modification. However, despite *conation* or behavior change being the ultimate goal, research suggests that product warnings mainly influence the primary and intermediary steps along the continuum of information processing namely, *cognition* (awareness, knowledge and comprehension) and *affect* (attitudes or perceptions) (Krugman, Fox and Fischer 1999). The goals of a product warning may be realized by communicating information that accurately, appropriately and adequately conveys information about the risks of the product, rather than scaring consumers away from using it. The challenge for policy-makers and warning designers is to uncover these parameters of adequacy, accuracy and appropriateness.

Prescription pharmaceuticals differ from most other consumer goods in their direct impact on public health. These products are essential in combating disease. However, if taken incorrectly or inappropriately, they may result in negative consequences. It may be argued that lay consumers still lack the technical wherewithal

to comprehend much of the information related to prescription drugs. Therefore, the perceived social, physiological and psychological risk associated with prescription drug utilization may be greater than with other products. Not surprisingly, the physician traditionally assumed sole responsibility for patients' therapeutic decision-making (Perri, Shinde and Banavali 1999).

More recently, however, there has been a dramatic change in the health care delivery process in the U.S. The advent of managed care organizations and the societal momentum towards more informed and participative health care decisions have supplanted the conventional dominance of the physician. Recognizing this paradigm shift in the health care environment, manufacturers are supplementing their conventional promotional efforts with more innovative marketing methods. Direct-to-consumer advertising (DTC) is one such marketing method that aims to accelerate the diffusion and adoption of newer therapies.

There are multiple variants of DTC advertisements. Most commonly used are ads that mention the name of the brand and the condition for which it is indicated. These are known as "product-specific" ads. Prior to 1997 FDA guidance on DTC, pharmaceutical companies were required to incorporate, in all prescription drug advertisements, an extensive disclosure of risk and warning information associated with drug use (Morris, Mazis and Brinberg 1989). This is known paradoxically as the "brief summary". Realizing the obstacles faced by manufacturers in providing such cumbersome information in time-constrained television or radio ad spots, the FDA allowed ads in the broadcast media to provide only a statement of the "major" risks

associated with product utilization as an alternative to the brief summary. The FDA guidelines also entailed that manufacturers make "adequate provision" in broadcast DTC ads for consumers to obtain complete drug prescribing information by mandating the provision of four different sources of information in these ads, namely a toll-free telephone number, an Internet website, a concurrent ad for the drug in a print media source that is comparably disseminated and a statement asking consumers to consult a physician, pharmacist or other health care professional for further information (Pines 1999). Further, all DTC ads are required to provide a "fair balance" of risk and benefit information.

Product-specific ads in the print media are still required to feature the extended disclosure of risk information in the "brief summary". Generally, the brief summary is displayed on the reverse side of the promotional message (FDA 1997; Kopp and Bang 2000). The information contained in the brief summary is similar to that featured in the patient package insert accompanying the prescription. The purpose of this brief summary is to provide consumers with adequate information about the drug to the extent that they may talk to a doctor about its appropriateness for their condition.

DTC ads have attracted much criticism for potentially misleading consumers by not adhering to the fair balance requirement. This has occurred mainly in relation to an over-emphasis on drug benefits and an under-emphasis on drug risks. Specifically, there have been some concerns about the ability of the brief summary in DTC ads to clearly and adequately deliver accurate information about the risks of taking the drug (Ehrlich 2003). Some view the brief summary as an overload of technical information in

fine print that is of little substantive use to consumers and therefore an unnecessary part of print DTC ads (Kaplar 1998). Others regard the information in the brief summary as "very important" and believe that it is incumbent upon drug manufacturers to find an effective method of providing this information in the print media (Wechsler 1998). This debate has stimulated consumer advocates and policy-makers to demand a re-examination of the current state of consumers' comprehension and use of the brief summary in health care decisions.

1.2 Problem Statement

The extent to which the brief summary in DTC advertisements may effectively communicate risk information is rapidly evolving into a critical question for regulators and policy-makers. Indeed, the FDA has emphasized that effective communication of drug risk information in the brief summary of print DTC ads is an immediate priority on its research agenda. The importance accorded to assessing the effectiveness of the brief summary in DTC ads is in apparent response to a growing concern that the status quo is inadequate in educating consumers about the deleterious effects of the medicines they take. Perhaps, the pharmaceutical industry fears that presenting a fair balance of risk and benefit information may highlight the negative attributes of its products. Critics of DTC advertising believe that DTC ads present a mostly one-sided view of product benefits versus risks. These groups point to recent examples of inadequate risk communication, such as GlaxoSmithKline's Paxil® ad, which inaccurately

claimed that the drug was non-habit forming, and Pfizer's ad for Lipitor®, which presented an unbalanced depiction of product benefits in comparison to risks.

Despite the awareness that more comprehensive research is needed to address the issues involved in risk communication, relatively little attention continues to be devoted to learning how consumers comprehend and use risk information from DTC ads. Thus far, the literature on risk communication in drug ads focuses solely on the characteristics of risk information present within the promotional copy. For example, studies investigate the effect of differential placement of risk information in DTC ads (Wogalter et al. 2002). Other studies evaluate consumers' interpretations of expressions of the frequency of side effect occurrence (e.g. seldom vs. rare) (Davis 1999). However, little knowledge exists regarding the contribution of the brief summary to consumers' perceptions of the risk associated with the advertised product. Does the brief summary supplement the risk information provided in the promotional copy? Are different formats of the brief summary associated with different evaluations of the overall risk information in the DTC ad? Do consumers prefer a certain format of brief summary to others? These questions warrant greater attention from a public policy standpoint.

Marketers may be wary of the effect of presenting product risk information on consumers' perceptions of product benefits. In this context, several studies across product categories examining the impact of consumers' perceptions of risk information in disclosures or disclaimers, document resulting unfavorable product attitudes. However, the extant DTC research omits analyzing whether and how consumers

engage in a trade-off between product risks and benefits after processing risk information in DTC ads. Perhaps, risk information in the brief summary may enhance the overall believability of the information in the ad. That is, presenting an unbalanced view of the benefits of the drug versus risks may lead consumers to attribute this information to the manufacturer's desire to sell the product. On the other hand, when extensive negative information about the drug is presented in conjunction with the benefit information, consumers may perceive the manufacturer's advertising claim to be credible. From a pharmaceutical manufacturer's perspective, it is imperative that the influence of consumers' level of comprehension of risk information on their attitudes towards the ad and brand be subject to investigation. Therefore, this study has important implications from the perspective of the manufacturer, consumer and the government.

1.3 Study Objectives

In an attempt to address the issues raised in the problem statement, the current study focuses on two broad objectives.

1) To measure the effect of incorporating a brief summary in print DTC ads on consumers' knowledge, attitudes and behavioral intentions.

Existing and proposed variants of the brief summary will be employed to test their influence on knowledge, evaluations of quality of risk and benefit information, ad

believability, attitudes toward the ad and brand, perceived product risk and intention to use ad information in making health care decisions. Specific research questions are:

1a) What does the brief summary contribute to consumers' drug-related knowledge, evaluations of ad information, ad believability, attitudes towards the ad and brand, perceived product risk and intention to use ad information in making health care decisions?

1b) How do consumers' drug-related knowledge, evaluations of ad information, ad believability, attitudes towards the ad and brand, perceived product risk and intention to use ad information in making health care decisions differ across formats of brief summary?

2) To develop a model that studies the relationship between risk information provision in the brief summary and brand attitudes.

The framework of attribution theory and previous research in risk communication will be employed to test competing models. We will test specific mediators of the effect of processing risk information on brand attitudes.

2a) What effect does the presentation of the risk information have on brand attitudes?

2b) Do consumers' risk perceptions mediate the effect of risk information on brand attitudes?

2c) Within the framework of attribution theory, do consumers' perceptions of ad believability and attitudes towards the ad mediate the effect of risk information on brand attitudes?

1.4 Justification of Research

Understanding consumers' processing of risk, warning and adverse effect information is especially critical in the domain of prescription drugs because of the importance of this information to public health. Therefore, this program of research has potential ramifications for shaping regulatory policy in prescription drug advertising. Considering the exponential increase in the number of drugs being advertised in this fashion, the potential for miscomprehension and confusion among the public is great. In turn, this may result in poor decision-making by consumers. For example, they may attempt to pressurize the physician to prescribe an advertised brand that may not be appropriate for their diagnosis. Alternatively, they may not adhere or comply with the physician-recommended drug regimen. Moreover, patients may believe that an advertised drug may be a panacea for their ills. However, it must be remembered that even in cases where an advertised prescription drug is appropriate, there may be side effects that are unique to certain types of patients that warrant more detailed communication.

The literature in health care marketing suggests that information from DTC ads encourages consumers to inquire about and specifically request drugs from their doctors. There are concerns that drug inquiries and requests that are not based on a

thorough understanding of the risks of drug use may exert a strain on the physician-patient relationship. The physician may decide that the product is unsuitable for the patient's condition and consequently may not prescribe the product. This may lead to patient dissatisfaction that may manifest itself in "doctor-shopping" behavior. Given this possibility, physicians may feel compelled to prescribe the requested drug.

Prior research suggests that consumers' may have many miscomprehensions about prescription drugs. These studies provide some insights into consumer processing of risk information and its impact on attitudes towards the risk information. They provide a conceptual framework upon which the effects of format and information clarity on consumers' information processing are based. However, there is little knowledge about which formats of information result in the most favorable outcomes.

The literature in communication of prescription drug information to consumers clearly demonstrates that inaccurate information processing may lead to negative medication-related outcomes, such as compliance and persistence. This underscores the need to ascertain which formats of risk information would prove more useful to consumers while adhering to a fair balance of risk and benefit information. Addressing this issue assumes even greater significance since it is possible that consumers engage in a trade-off between drug risks and benefits. For instance, it has been reported that increasing the amount and specificity of risk information results in increased awareness of risks but decreased knowledge of benefits (Kopp and Bang 2000).

Assessing consumers' beliefs, evaluations and thereby their attitude formation regarding the risk information in drug ads will help practitioners and researchers gain a

better understanding of how such information may influence consumers' medication-related behaviors. It will help marketers recognize how best to convey risk information such that it is clear and understandable. The provision of drug risk information in DTC ads in a clear and objective manner may provide consumers the opportunity to assimilate and process the risk information prior to making a decision (e.g. drug inquiry or drug request). In addition, the information in the ad may assist physicians in explaining to the patient the rationale behind their prescribing decision.

There is a considerable body of research evaluating the impact of DTC advertising on several outcomes such as the attitudes of consumers and health care professionals, its impact on sales, and its influence on patient-physician relations. Nevertheless, an important component of consumers' DTC ad processing – risk information - remains unclear. Even the few studies that have considered the impact of risk information presentation in DTC ads have focused specifically on the information featured within the promotional copy. Little empirical research on the impact of risk information in the brief summary has been undertaken. The present study attempts to fill this void in the DTC literature by examining a very important but often overlooked component of the risk information in print DTC ads.

1.5 Organization of the Research

The dissertation consists of six main chapters detailing different aspects of the study. Chapter 1 consisted of an introduction to the research topic, problem statement, study objectives and justification of the research. Chapter 2 discusses the literature in

communication of risk information in DTC ads and other product categories and offers some insights into established conceptual frameworks of information processing. The review of the literature forms the basis for generating research hypotheses and the development of the theoretical models that will be tested here. These are described in Chapter 3. The research design and analysis plan for the study constitute Chapter 4. Chapter 5 summarizes the study results. Chapter 6 contains a detailed discussion and implications of study results; lists the limitations in the study and offers directions for future inquiry. A bibliography of study references and an appendix of tables and figures follow the final chapter.

CHAPTER 2

LITERATURE REVIEW

2.1 Direct-to-consumer Advertising

The phenomenon of direct-to-consumer (DTC) advertising of prescription medications is now very familiar to most Americans (Palumbo and Mullins 2002). From a relatively ambiguous beginning in the mid-1980s that was marked by consumers' confusion about the information in the ad, health care professionals' displeasure at being potentially replaced as the sole source of drug information for patients and, numerous public health concerns on the part of the U.S. Food and Drug Administration, this practice has grown exponentially. Until a few years ago, DTC drug advertising was a concept unique to the U.S. health care system. More recently, however, this practice has been adopted in New Zealand. In addition, a variant of DTC advertising is being experimented with in the U.K. where communications are directed towards only those consumers who are actual users of the prescription product and not the public at large. Australia is also experimenting with this relatively new form of promotion (Menon et al. 2003).

During the formative years of DTC advertising in the U.S, research focused mainly on issues such as the influence of these ads on the dynamic of the patient-physician relationship, the attitudes and acceptance of DTC advertising by consumers

and the association of DTC ad expenditures with increased drug prices (Krieger 1983; Masson and Rubin 1985). DTC advertising was criticized for potentially trivializing the use of prescription drugs and fostering the use of prescription drugs in an arguably over-medicated society (Mastroni 1984). Accordingly, the early research in DTC advertising aimed at developing policies that could curb the growth of this practice and restrict its influence on consumers, who were deemed to be inadequately qualified to process prescription drug information.

An impressive array of studies has attempted to gauge the impact of DTC advertising on various aspects of health care delivery in the U.S. Much of the extant research postulates on the merits and demerits of DTC ads for public health. In addition, the opinions and perceptions of the various health care industry stakeholders (patients, providers, payers, manufacturers and regulators) about DTC advertising have been the subject of much discussion. Nevertheless, the question of whether this advertising is actually effective remains less clear. It may be argued that DTC ad effectiveness is a moot issue considering the pharmaceutical industry's willingness to spend large sums of money on this practice (Brichacek and Sellers 2001). Several DTC ad campaigns have generated positive return-on-investment in terms of drug sales (Findlay 2001). However, many others have not been as successful. In the following paragraphs, we discuss the evidence of DTC ad effectiveness unearthed by past research.

Studies report that DTC ads increase consumers' top-of-mind brand awareness (Roth 2003). Awareness levels of the most heavily advertised drugs such as Viagra®,

Lipitor® and Celebrex® are extremely high (*Prevention* 2002). Consumers not only recall the name of the advertised drug, but are able to accurately match them with the indicated medical condition (Balazs, Yermolovich and Zinkhan 2000, Prevention 1999). Further, there is compelling evidence that this form of promotion makes consumers more aware of several disease conditions that they may not have been aware of previously. In turn, DTC ads may help increase the detection and reporting of medical conditions.

In the past, DTC research has focused on the attitudes of the multiple stakeholders in the health care arena towards this practice. For example, it is generally well acknowledged that while consumers have a favorable opinion of DTC ads, providers have generally been critical of the practice (Alperstein and Peyrot 1993; Deshpande et al. 2004; Morris, et al. 1986; Perri and Nelson 1987; Perri and Dickson 1987). Payers generally believe that DTC ads stimulate unnecessary and more expensive health care utilization. Therefore, it is not surprising that this segment of the health care industry attempts to restrict the influence of DTC ads by introducing stringent prior authorization procedures and formulary controls for heavily advertised drugs (Perri, Shinde and Banavali 1999).

From a manufacturer's perspective, DTC advertising seems to have worked very effectively. For instance, it is well known that DTC efforts have reaped positive rewards in terms of brand sales. Further, most DTC ad campaigns have generated positive return-on-investment, justifying the investment into this practice (Basara 1996; Findlay 2001). DTC marketing of prescriptions has also stimulated increased physician office

visits and requests for the advertised drugs (Alperstein and Peyrot 1993; Deshpande 2004; Zachry et al. 2002). In fact, a series of surveys by *Prevention* magazine suggests that the increasing numbers of patients seeing their doctors and requesting advertised prescriptions has led to greater willingness on the part of physicians to acquiesce to patient demands. While DTC has been successful in the diffusion and adoption of innovative drug products, it also plays a central role in reducing post-prescription dissonance by aiding consumers' information search activities (Menon et al. 2002). Indeed, it may be argued that DTC has led to the greater consumer adoption of technological innovations such as the Internet in seeking information about prescription medications. Apart from the Internet, other channels such as toll-free telephone numbers have also found increasing use as information resources owing to their prominent display in DTC ads.

Notwithstanding the success of DTC from multiple perspectives, it remains clear that the debate about its appropriateness and usefulness for patients will continue, especially considering the upcoming implementation of the Medicare prescription drug benefit plan. The crux of the debate has to date revolved around the effect of DTC ad budgets on the ultimate retail price of the prescription. In this regard, Calfee (2002) points out that DTC ads account for a much smaller piece of the pharmaceutical industry's promotional pie than detailing and sampling to physicians. Empirical evidence complementary to this contention has been provided by Rosenthal et al. (2002), who reveal that DTC ad expenditures contribute much less to the ultimate cost of the drug than expenditures on research and development and promotion to physicians. From a

different perspective, Kopp and Sheffet (1997) theorize that while DTC may add to the wholesale price of the drug, competition at the retail level would serve to drive prescription prices lower, being offset by reductions in retail margins. On the other hand, Findlay (2001) and Lexchin and Mintzes (2002) argue that there is irrevocable evidence that the expenses associated with DTC advertising are "passed on" to consumers in the form of increased drug prices.

Another central issue in the policy debate that has enveloped DTC advertising is its ability to communicate effectively information about drug risks and side effects in a balanced and appropriate manner. It may be argued that manufacturers are simply complying with mandatory risk disclosure requirements without bothering to assess if this risk information is clear or comprehensible to the end users. It is hypothesized that drug-makers may try to shy away from a full and comprehensive provision of risk information due to the fear that greater risk information may instill a sense of apprehensiveness about the drug among consumers. Still, the information about drug risks and side effects is an essential component of the drug's attributes and may profoundly influence consumers' medication-taking behaviors. Consequently, it is imperative that this information be communicated in a user-friendly manner to consumers. However, the extant literature has omitted analysis of consumers' processing of risk information from DTC ads. The stagnant state of research in this area and the potential ramifications of the evidence that may be uncovered from investigating consumers' processing of risk and side effect information warrants a conclusive examination of the effectiveness of risk communication in DTC advertising.

2.2 Risk Communication

Risk and warning communication serves to deliver information regarding the safe and effective use of the product (deturck 1989). Laughery and Hammond (1999) state that there are several levels in the communication of risk and warning information. At a primary level, risk communication promotes safety by simply informing individuals of the risks associated with any particular behavior. Subsequently, it encourages consumers to engage in safer behaviors. Finally, it impacts consumers' beliefs and value system about the behavior. In turn, this may lead to behavioral modifications (Laughery and Hammond 1999)

The practice of risk communication has received considerable attention across literatures. Risk communication has been variously defined in previous research. For example, Covello and Mumpower (1985) broadly state that risk communication implies *"...any purposeful exchange of scientific information between interested parties regarding health or environmental risks".* Plough & Krimsky (1987) employ a more specific definition of risk communication. According to these authors, the concept of risk communication consists of five elements namely, "*intentionality, content, audience directed, source and flow"***.** They describe risk communication as either symbolic or conventional in nature; the conventional risk communication construct is *"…any public or private communication that informs individuals about the existence, nature, form, severity, or acceptability of risks"* and includes measurable variables while the symbolic dimension comprises of "cultural and experiential inputs"*.* According to these authors, not only does risk communication consist of any transmission of information that is

deliberate and has definite goals but also of any unplanned consequences of "informal risk messages" (Plough & Krimsky 1987).

The communication of risk information has received attention across several product categories. The most widely examined area of risk communication is in the alcohol and tobacco product categories. The scope of the research question investigated in the current project specifically encompasses risk information conveyed by manufacturers in prescription drug advertisements. Accordingly, the practice of risk communication under review in the subsequent sections is restricted to communications (voluntary and mandatory) from the product manufacturer.

2.2.1 Risk Communication in non-pharmaceutical products

The extant literature in non-pharmaceutical product risk communication is discussed in several stages outlined by McGuire's information processing framework (McGuire 1985). First, the effectiveness of risk communication on attention and awareness is discussed, followed by an examination of its impact on product knowledge and comprehension. Finally, we discuss risk communication in terms of its impact on affect and ultimately behavior.

Awareness and Attention

Research in alcohol and tobacco advertising has shown that warnings on labels or in product ads moderately increase consumer awareness and knowledge about product risks. For example, Greenfield, Graves and Kaskutas (1993) report that

approximately a third of consumers were aware of warning information, 18 months after introduction of alcohol warning labels. Scammon, Mayer & Smith (1991) also report a significant increase in warning label awareness after the introduction of alcohol warning labels. However, despite the heightened awareness of warning and risk information of alcohol and tobacco products, the literature suggests that consumers' attention to these product warnings is limited. Research by Fischer et al (1989) shows that almost half of their study population does not attend to health warnings and among those who attend to the warnings, recall of the message was low. Further research by Fischer et al. (1993) reveals that consumers cannot maintain attention on warning messages in alcohol and tobacco ads sufficient for adequate information processing. Presence of fictional characters such as "Joe Camel" in the promotional material were found to detract from the amount of time consumers spent reading a warning message within the same ad. Warnings in cigarette ads are more effective at attracting and marinating attention than warnings in alcohol ads (Fletcher et al., 1995, Fox et al. 1998). There is also evidence that purports the development of "wear out" among consumers due to overexposure to these warning labels (Krugman et al. 1994).

Some studies suggest that attributes of the warning labels related to format characteristics such as the location, content and shape do not operate as determinants of attention to the warning (Fischer et al. 1989). Conversely, other studies show that the format of warnings does play an important role in information processing. In particular, it is conjectured that it may impact the noticeability and attention to warning messages. Studies by Barlow and Wogalter (1993) and Laughery et al. (1993)

demonstrate that noticeability of warnings in alcohol advertisements and alcohol product labels on can be improved by employing format changes. In this regard, some key predictors include warning conspicuousness, use of color, pictures, icons, fewer characters per square inch, less background clutter and mentioning credible sources like "Government warning" in the message title. Similarly, Swasy, Mazis and Morris (1992) find that isolation of the warning message, increasing warning size and decreasing number of characters per inch helped increase noticeability of the alcohol warning. Research in communication of alcohol warnings shows that employing more than a single mode of communication, such as video and audio, in warning messages, may be extremely effective in eliciting attention and stimulating recall (Barlow and Wogalter 1993; Ducoffe 1990). The timing of the warning messages, before or after the promotional message is inconsequential to elaboration of message arguments (Barlow and Wogalter 1993; Slater et al. 1999).

Knowledge, comprehension and retention

Previous work by MacKinnon and Lapin (1998), and Snyder and Blood (1992) note that presence or absence of promotional material does not change recall and knowledge of warnings. From this perspective, it may be inferred that presence of promotional messages along with the warnings does not detract from processing of warning information. Indeed, consumers may be able to process a message featuring both positive and negative information about the product. Greater specificity and severity of messages is associated with greater recall of alcohol warnings, e.g. warnings

with birth defects are recalled more than warnings about traffic fatalities on alcohol labels (Scammon, Mayer and Smith 1991).

Research on television ads shows that fear or threat appeals not only serve to increase the likelihood of attention but also influence information processing by increasing consumer knowledge of warnings (Slater et al. 2002). Audio-only or dual-mode warnings perform better than video-only warnings at facilitating recall and increasing knowledge of alcohol warnings (Smith, 1990). A readability analysis of tobacco and alcohol warnings reveals that a college graduate-level reading comprehension may be required for optimal processing of the warning message (Malouf 1992). The use of quantitative information in alcohol warnings increases warning recall (Slater et al. 1998). However, the use of behavioral recommendations instead of the likelihood of negative outcomes seems to decrease recall of the warning messages (Slater et al. 1998).

Popper and Murray (1989) find that changes to the format of the warning such as increase in font type (from 10-font to 14-font) or increase in overall warning size or color does not have any effect on consumers' recall and recognition of the warning message. These differences may have been masked by the study design i.e. forced exposure and attention. Possibly, the manipulations employed in the study were not extreme enough to elicit differences in information processing. However, some of these results find support from a study by Fischer et al. (1993) who find very little advantage of using a colored (yellow) background for the warning message as opposed to the standard black and white contrast.

Believability and Attitude towards risk information

Outcomes such as believability & attitude towards risk information are an integral component of measuring risk communication effectiveness. Content of the warning such as severity, specificity and message framing all influence how warnings are processed. For example, Laughery et al. (1991) demonstrate that warnings explicitly listing health outcomes are perceived as more believable than those not listing health outcomes. Andrews, Netemeyer and Durvasula (1992) find that warning labels with serious outcomes such as birth defects elicit favorable opinions. Use of credible sources such as "Surgeon General" and personalization of warnings generates a favorable attitude towards alcohol warnings (DeCarlo et al. 1997). Loken and Howard-Pitney (1988) find that specific warnings detracted from the persuasive appeal of the tobacco advertisement (Loken and Howard-Pitney 1988). Furthermore, specific warnings elicit less favorable opinions on attractiveness and credibility.

Perceptions of believability of warnings differ by characteristics related to the receiver of the communication. For example, perceptions of alcohol drinkers regarding warnings are more likely than non-drinkers to fall within a "latitude of rejection" (DeCarlo et al. 1997). This implies that the two groups differ in terms of the perceived believability of the message. Familiarity with the warning message and the specificity of the message help increase its believability (Beltramini 1988). However, Crane and MacLean (1996) report that older and more traditionally-worded warnings elicit lower believability and effectiveness scores as compared to newer warning labels. On the other hand, message specificity and personal relevance do increase the perceived

believability of the message. Warnings that list consequences of smoking are perceived as more believable as compared to warnings that suggest specific behaviors that decrease risks associated with smoking (Beltramini 1988).

Prior attitudes and beliefs exert an important influence on believability and attitudes towards alcohol warnings (Andrews, Netemeyer and Durvasula 1991). Perea and Slater (1999) find that women prefer collectivist warnings i.e. warning about risks to friends and family, while men prefer warnings with individualistic appeal i.e. warnings citing risk to oneself. However, perceptions were overall more favorable for the collectivist warnings as compared to individualistic warnings. Increased message believability leads to more favorable attitudes towards the message (Andrews, Netemeyer, Durvasula 1991). Research in tobacco advertising has shown that incorporation of quantitative information increases believability of ads and helps engender positive attitudes towards warning messages (Slater et al. 1998). Providing such information may serve to increase message credibility, decrease ambiguity and induce favorable cognitive responses.

Warning research assessing the influence of source credibility has found that media portrayals of celebrities decrease the positive impact of warning messages by potentially trivializing the seriousness of warning information. There was concern over the use of a cartoon figure of Joe Camel in tobacco ads. Due to the widespread concern and debate over the use of Joe Camel, manufacturers were forced to retire Joe Camel from their ads (Fox et al. 1998).

Behavioral Intentions and Behavior

Impact of risk and warning messages on consumer behavior has also received attention in the risk communication literature. More consumers reported being careful after implementation of alcohol warning labels and taking precautions while driving after drinking (Greenfield, Graves and Kaskutas 1993). Hankin, Sloan and Sokol (1998) find that drinking decreased among pregnant African-American women after introduction of alcohol warning labels (Hankin, Sloan & Sokol, 1998). However, some studies have found that warnings may have a potential "boomerang effect" (Snyder and Blood 1992). According to the "forbidden fruit theory", warnings may make the advertised product seem more appealing. However, other studies that test the boomerang effect (MacKinnon and Lapin 1998) find no evidence such an effect on product perceptions and intention to use the product. Greenfield, Graves and Kaskutas (1999) find that compared to an unexposed group, individuals exposed to alcohol warning labels engage in conversations regarding negative effects of alcohol and also indulge in safer behaviors as a result of information from alcohol warnings. The above studies provide some evidence to the contention that warnings work by modifying risky behaviors.

2.2.2 Risk Communication in pharmaceuticals

Several studies in this area (discussed below) assess the effectiveness of instructions in the PPI (patient package insert), PIL (patient information leaflets) and prescription package labels on patients' knowledge, beliefs, attitudes and finally

compliance. The literature on communication of prescription drug information provides contrasting evidence regarding the efficacy of conveying risk information to consumers. The existing format and content of the information on drug warning labels or auxiliary pamphlets have been found to contribute significantly to patient non-compliance (Morrell, Park and Poon 1989). Further, the clarity of the risk information has been criticized for its negative impact on consumers' likelihood of use of prescription drugs. However, one study reports that three-fourths of the study population perceived the prescription drug risk information in drug pamphlets to be useful (Ferguson, Discenza and Miller 1987). Ferguson, Miller and Discenza (1987) demonstrate the positive effects of message variables e.g. strength of the warning, on patients' compliance with their medications. Stronger warnings were found to favorably impact patients' beliefs about usefulness of the information. However, using a highly credible source like the FDA did not significantly influence consumers' perceptions of information usefulness. Studies suggest that men favor stronger warnings whereas women find stronger warnings less useful.

Research by Keown (1983) revealed that most consumers rated the package insert for a hypertension drug as fairly easy or very easy to read. Most study participants were able to distinguish side effects on the basis of their severity and seriousness. However, side effects that were of low and medium seriousness were not discriminated to a great extent (e.g. tingling vs. nausea). However, most subjects did not perceive many differences in risks with regard to the differing probabilities. Drugs that had a greater number of side-effects were perceived to be riskier than drugs with

lesser side effects. Unlike, results of the Ferguson, Miller and Discenza study (1987); Keown (1983) found a significant relationship between risk perception and intention to use the drug. Morrell, Park and Poon (1989) also find the presentation of prescription drug information in the prescription drug label to be ineffective in consumers' ability to accurately process drug risks. They also found that prescription drug labeling is often misinterpreted by patients. Several other studies have found prescription drug labels to be ineffective in providing patients with necessary drug information (Potterton 1984, Widerholt, Kotzan & Cooper 1983).

Morrell, Park and Poon (1990) investigate the utility of pictorials and symbols in conveying prescription drug information. They also examined moderating roles of consumer characteristics such as age on information processing of pictorial information. Their results reveal that memory of the information improved in younger consumers by using a mixed format (verbal and pictorial); however, older adults do not seem to be influenced by the use of pictorials. Presenting negatively-framed information about the consequences of using the drug enhances compliance intentions (Bower and Taylor 2003).

2.2.3 Risk Communication in DTC advertising

The government currently mandates provision of risk and warning information for several product categories such as alcohol and tobacco products as well as for prescription drugs. However there exist several differences between these product categories. 1) Prescription drugs have a direct and beneficial impact on public health.

Unlike prescription drugs, tobacco and alcohol products do not have any significant health benefits associated with consumption. 2) The primary objective of alcohol and tobacco warnings is to deter both users and non-users of these products from consumption. However, while conveying risk information in prescription drug ads, one has to consider the negative influence of this information on product users, who may scare away from using these products and thus be non-compliant with their prescribed therapy. Even for consumers currently not using the advertised prescription brand, the risk information has to be conveyed in a manner that does not scare them, but at the same time provides them with an unbiased picture regarding potential risks associated with product use. 3) There are several *unique* side effects associated with each drug, which need to be taken into account while making decisions regarding prescription drugs. Provision of "general" warning statements such as those used in certain product categories such as tobacco or alcohol advertising will not adequately convey all risks associated with prescription use. The risk information is different for each prescription drug and needs to be completely explained. 4) Consumers know relatively little regarding prescription products and risks associated with their use. Comparatively the knowledge of risks associated with consumption of tobacco and alcohol products is widespread even among teenagers. The informational content of risks for prescription advertisements is more technical in nature and thus information processing and comprehension levels for these two types of advertisement will differ largely. 5) Moreover, information processing differs across the two categories of advertisements since the target audience for tobacco and alcohol warnings is predominantly

adolescents, young and middle-aged consumers, whereas for prescription drug warnings it is predominantly the elderly, since they are the heaviest users of drugs. 6) In case of prescription drugs, the physician serves as a gate-keeper to product use, the other product categories such as alcohol and tobacco products do not need any one to authorize use of these products (except age-related restrictions).

Due to the above reasons, the provision of risk information such those used in tobacco or alcohol advertising will not adequately convey the complete risk profile associated with the use of the advertised prescription product. The complex nature of prescription drugs and the several and varied beneficial and negative effects they may have necessitates the provision of product risk and warning information that is markedly different from other product categories, not just in its content, but in the fundamental purpose that underlies its provision – to educate, inform, protect and improve health.

Risk communication is a therefore vital element of DTC advertising. Complete and understandable risk disclosures in DTC ads can potentially help all stakeholders in the heath care decision-making process, namely consumers, policy-makers, health care providers and manufacturers. Provision of complete risk information will educate consumers and help make more sound decisions regarding product use. They can potentially alert consumers to side effects they should expect while taking the prescription drugs. This helps reduce the disease burden of drug-induced side effects, as consumers will be better informed and thus more proactive in seeking medical help when serious side effects are observed. Risk disclosures in DTC ads thus serve to supplement risk information in patient package inserts. This has important implications

for heath care providers too, as it creates a more informed consumer who has the necessary risk and benefit information regarding products and can benefit form the prescribed treatment. Drug requests will not be made merely on basis of benefit claims in the ad and peripheral cues like celebrity endorsers. The consumers due to their knowledge of product risks will be able to weigh consequences before they make a request for the advertised product. Physicians will not have to spend their time clearing consumer misconceptions regarding product risks. Complete risk disclosures will help policy-makers ensure that all necessary product-related information is provided to the consumer. This will ensure completeness and balance in ad information regarding product attributes.

Full disclosure of risk and warning information in DTC ads is extremely important not simply from the public policy perspective of providing consumers with important information that can facilitate medication-related behaviors such as compliance and adherence, but also from the perspective of the drug manufacturer, because it gives consumers the "big picture" relating to the effectiveness of the drug. For consumers, the effectiveness of the drug may not be fully understood until the extent to which the risk it presents to their health remains vague or ambiguous. Consumers who perceive that the information in the DTC ad is incomplete may disbelieve the information about the benefits of the drug. Such perceptions will then negate the drug maker's over-emphasis on the product benefits because consumers may not use it in their discussions with the healthcare professional. After all, the basic purpose of DTC advertising is to create greater awareness of the advertised product and provide consumers with

information that is adequate for them to initiate a product-related discussion with their healthcare professional. If consumers perceive that the provided information is incomplete, inaccurate or unbalanced, they may not pay attention to any information that is contained in the ad. This may negatively affect their attitudes toward the ad and the advertised brand. Furthermore, they may believe that they do not possess an adequate amount and quality of information with which they may be able to initiate a discussion with their healthcare provider about the appropriateness of the drug.

Taking into consideration the pressure on Congress to pass a drug benefit plan for Medicare, regulators and lawmakers are scrutinizing the actions of the drug industry more closely than before. In fact, the widely publicized potential association between burgeoning DTC expenditures and rising drug costs has become a stick which regulators are wielding to pressurize the industry into reducing the prices of block buster drugs. The media and patient advocacy groups are also closely examining the DTC ads for any violation that they may contain. The widespread attention that infringements of FDA guidelines receive in the media may adversely affect the image of the pharmaceutical manufacturer, which may be accentuated by the prevailing negative attitude towards the pharmaceutical industry in general. The challenge facing regulators and policy-makers is to find an effective "middle ground" to communicate risk information such that it does not overwhelm consumers and at the same time provides the risk information necessary to determine the appropriateness of the drug.

Prior research in risk communication has examined consumer processing of information from DTC advertisements. Davis (1999) conducted mall intercept surveys to

determine how consumers interpret "imprecise frequency descriptors" (such as rarely, commonly, and frequently) in direct-to-consumer advertisements. The results of these surveys demonstrate that although consumers differentially interpret each of these imprecise frequency descriptors, there exists much variation in consumer perceptions. Consumers overestimated most side effects tested in the study (with the exception of "soreness in arm") (Davis 1999). Typically, DTC ads order side effects in the copy based on their incidence levels. For the majority of DTC ads, greater than 50% of consumers did not interpret the first side effect listed as the most common side effect. Results from the Davis study suggest that there is great degree of miscomprehension of risk and side-effect information in DTC ads. However, this study only tested comprehension of risk information on the promotional page of the ad and ignored the brief summary, which also comprises of a vast amount of risk information.

Another study by Davis (2000) sought to develop an operational definition of "complete" risk information. His results reveal that respondents consider only risks that have an incidence greater than 3% to be necessarily communicated in DTC ads. However, the study used undergraduate students as subjects for eliciting preferences for risk information and thus results are not generalizable to the population of prescription drug users (which mainly comprises of the elderly). A second objective of Davis's study was to determine how varying degrees of completeness of risk information influence consumers' purchase intentions. All respondents were receptive to ads containing risk information. However, ads with incomplete risk information elicited higher purchase intention scores. Respondents described the drug with incomplete risk

information as safer than the drug with complete risk information. When asked to select either the drug with complete or the drug with incomplete risk information, respondents favored the latter. However, this does not imply that consumers do not like risk information in ads, since they were not aware that one of the profiles of the drug presented to them was incomplete. They may have selected the drug with incomplete profile simply because that drug did not have any other side effects.

Studies by Morris et al. (1986, 1987, and 1989) revealed that the information processing of risk information varied with respect to the disease state for which the advertised drug was indicated. Presentation of complete risk information for serious conditions was perceived as useful. For conditions perceived to be milder, the presentation of complete risk information was perceived as unfavorable. Overall, incorporation of risk information in the promotional message increased the credibility of the ad. Source of communication had a bearing on knowledge attained from the ad. Drug leaflets was processed by assimilation into the existing knowledge structure which was established by greater scores on "implied" knowledge questions, whereas ad information was elaborated in lesser detail resulting in higher scores on "verbatim" questions. Morris et al. also revealed that format of information presentation had a significant impact on perceived usefulness and believability of ad information. The format with risk and benefit information integrated was perceived as more favorable than the separated format (Morris, Brinberg and Plimpton 1984).

Subsequent studies by Morris et al. (1986) examined misinformation using both open-ended and true-false questions across media (television and print). This study

reveals that there existed (in the 1980's) a significantly high level of miscomprehension (19%) among consumers regarding the information in DTC ads. The results of their earlier study were corroborated wherein inferential questions had higher levels of miscomprehension as compared to pure recall questions. A surprising finding was that although consumers who were specifically asked to pay attention to the ad stimuli had better memory for information conveyed, they reported a greater number of incorrect interpretations. This shows that greater elaboration on the messages causes greater miscomprehension. Subjects exposed to TV ads had better recall of ad messages. However, they reported more statements that were incorrect on the open-ended knowledge items.

Morris, Mazis and Brinberg (1989) varied risk disclosures in televised DTC ads and measured treatment effects in comparison to a control group where no risk information was provided. The processing of the risk information i.e. awareness and comprehension and consequently the effect it had on attitudes towards the information was shown to differ with the format, specificity and amount of risk information presented**.** Specifically, presenting increasing amounts of risk information to consumers causes increased risk awareness and knowledge; however, a "trade-off" in information processing is caused wherein either only benefits or risks will be processed properly. In a related study, Morris, Ruffner and Klimberg (1987) found that consumers find television DTC ads with no risk information as misinformative. Consumers approve of TV ads with risk information "dispersed" all through the advertisement. Brief and specific risk information when presented in this dispersed format was viewed as less

irritating than emphasized specific risks or integrated general risks (Morris, Ruffner & Klimberg 1987).

Cady and Larson (1989) found that the brief summary exerted significant attribution effects on college students' perceptions of ad believability. Although the effect was significant for an anti-depressant ad targeted at the elderly, attribution theory did not apply when the same drug ad was indicated for college students. Cady et al argue that this was probably due to a perception that college students do not need treatment for depression, thereby explaining the inconsequential effect of risk information on ad believability (Cady and Larson 1989).

Sullivan, Schommer and Birdwell (1999) compare product-specific and disease-specific DTC ads for Hytrin® indicated for Benign Prostratic Hyperplasia (BPH) based on consumers' retention of risk information. Overall, less than 20% of consumers retain risk information from the DTC ads. The researchers found no differences between the two groups of consumers exposed randomly to either of the two types of ads or a control group. However, post-hoc comparisons reveal differences among consumers based on past exposure to an ad for Hytrin® or history of Hytrin® use. Previous use of Hytrin® actually resulted in greater number of incorrect answers to the risk items, while previous exposure to ad increased the percentage of correct responses. These results support the need for further investigations into how the brief summary can add to the knowledge of risk information from the ad especially to consumers who are already taking the drug.

In another study, Sullivan (2001) compared consumers' evaluations of two ads for Nasonex® and Flonase®, which were both prescription allergy medications. However, the Nasonex® ad presented more risk information than benefit information as compared to the Flonase® ad. The results showed that consumers had better evaluations of the Nasonex® ad and believed it to be a more effective treatment for allergy. This could possibly indicate that consumers desire risk information in DTC ads, and positive perceptions of ads with risk information translates to positive brand perceptions. This has implications for marketers, as provision of clear, understandable and balanced risk information to consumers may enhance the perceptions of consumers towards the advertised product.

Wogalter et al. (2002) tested several hypothetical formats of presentation of risk and benefit information. This study manipulated information presentation by designing four ad formats with either integrated or segregated structure and colored format versus format with no color, and one format with enhanced features. The results reveal that the format with enhanced features and the format with combination of separated structure and color worked best in terms of knowledge of risks and benefits and effectiveness scores. Further analyses revealed that presence of color was key in predicting effectiveness as compared to separation. Across all formats, benefit information was recalled to a greater extent than risk information. Compared to younger adults, the elderly recalled very little information from the advertisement.

A study by Tucker and Smith (1987) using fictitious formats of warning disclosures found that DTC ads containing warning information were favorably received

by consumers and ads with brief summary information were judged to be more informative and valuable than those without the brief summary. However, ads with general warning messages were considered more reassuring. Perhaps, the format of the brief summary is not conducive to consumers' information processing and consumers may not be as desirous of the full disclosure of product-related risks in the format it is currently presented. Consumers may be overwhelmed by all the risk information that is currently in DTC ads although they perceive this information to be useful (Menon et. al. 2003). Consumers may also be confused by the inherent paradox in the information that is communicated to them since it may seem from the amount and specificity of the risk information in the ad that the drug causes more harm than benefit.

A content analysis of DTC ads by Roth (1996) reported that almost a third of all print ads in his sample actually violated the requirement of fair balance of risk and benefit information as stipulated by the FDA. A review of ads by health professionals revealed that the advertisements were deficient in risk and side effect information. Moreover, information regarding drug misuse was commonly omitted from DTC ads (88%).

Hochhauser (2002) analyzed brief summaries from ten DTC ads appearing in leading consumer magazines and found that most ads were written at grade level of 17+ (first year graduate school educational level). Most brief summaries had very low Flesch reading ease scores suggesting that these summaries are very difficult to read.

Most brief summaries had complex sentence formations and vocabulary. The low readability of these brief summaries is mostly attributable to their verbose format.

Several studies in DTC advertising show that consumers prefer seeing risk information in DTC ads. In turn, attitudes towards the advertisement and the promoted brand improve with better perceptions of the risk information in the advertisement. An analysis of survey data by Deshpande et al. (2004) involving comparison of effects of risk and benefit information found that the quality of risk information is more important than benefit information in evaluating the ad.

A recent study by Vigilante et al (2001) investigates consumer information processing of risk and benefit information on Internet websites of DTC advertised drugs. The authors note that consumers prefer segregation of risk information. When risk and benefit information are placed "higher in the website hierarchy" in a segregated format, accessibility and recall of the information is improved. These findings have important implications for the brief summary in print ads. It is important to discern consumer preferences for segregation or integration of drug information in the brief summary of a DTC advertisement. Presentation of information in the preferred format will facilitate greater recall and retention of such information.

Prevention magazine has conducted a series of national consumer surveys since 1997 addressing health issues affecting American families. A central theme of these surveys is Direct-to-consumer advertising and its impact on consumer behavior. The *Prevention* surveys show that consumers have positive opinions of both risk and benefit information in DTC ads. For example, in 2001, greater than 50% of consumers

evaluated risk information as "excellent" or "good". However, consumers still perceive the benefit information to be better than risk information (Figure 7). About 62% of consumers feel that DTC ads provide them with risk information they need to discuss the medication with their doctor, whereas 68% believe that the ads provide them with the necessary benefit information.

Consumers do not attend to brief summary in DTC advertisements. About 40% of consumers have never noticed the brief summary. Less than 15% of consumers exposed to an ad of interest read all the information in the brief summary. About 10% of consumers do not read any of the brief summaries even when the ad is of interest to them (Figure 8). Based on those who attend to the brief summary, only 35% of consumers perceive the information in the brief summary to be very clear and understandable (Figure 9). These results imply that consumers are not satisfied with the status quo of the brief summary in DTC advertisements. Specifically, almost half of the respondents are completely unaware of the existence of this summary of risks.

Prevention's results receive support from a recent FDA survey (FDA 2002), which reported that about three-fourths of respondents ignore the technical small print information in print DTC ads. About 60% of respondents in the FDA survey believe that DTC ads do not provide sufficient side effect, risk and warning information whereas only 41% believed that there was a lack of benefit information.

An extrapolation of the *Prevention* survey results to the entire population reveals that, since 1997, over 5 million consumers have been persuaded by DTC ads to talk to their doctor about the advertised medication. It may be argued then that such

interactions with the doctor which create the environment for specific drug requests may be based on an incomplete understanding of risk information. Although the brief summary presents the consumer with a vast amount of risk information, elaboration may be hindered due to the format, content and sheer volume of such information. It is vital to discern consumer preferences for presentation of such risk information. Greater knowledge of these preferences will help policy-makers and manufacturers tailor the brief summary to meet consumers' need for information. This may ensure greater attention, comprehension and use of important drug related risks, benefiting the multiple health care constituents, especially patients.

The literature in DTC advertising justifies the need for further research regarding the specific formats of risk information that may be more useful to consumers in providing a balanced presentation of risk and benefit information in DTC ads. Addressing this issue assumes even greater significance since it is possible that consumers engage in a trade-off between processing information related to risks and benefits. Specifically, studies reveal that increasing the amount and specificity of risk information results in increased awareness of risks but decreased knowledge of benefits. To some extent, it is possible that studies that investigated the trade-off between more and less risk information did not account for the objectivity, clarity and comprehensibility of the information, which may represent key drivers of consumers' perceptions of the risk disclosure. Nevertheless, exposure to such information has the potential to scare consumers away from taking these medications in an appropriate manner.

Studies have shown that consumers make judgments "beyond the information provided to them" in an advertisement (Kopp and Bang 2000). Consumers may develop negative attitudes towards the benefits of the drugs and shy away from talking to their doctors about a particular advertised brand. The risk information conveyed in DTC ads may induce fear appeals in the minds of consumers regarding the effect of the prescription drugs on their health, thus undermining benefits and potentially leading to non-compliance with the prescribed drug regimen.

The review of the literature suggests that the risk information in DTC ads is strongly associated with consumers' interpretations of the product's risks. Considering that the risk information in DTC ads may also ultimately exert a profound influence on doctor-patient discussions and prescription requests, it is imperative that balanced and clear risk and warning information be presented in DTC ads.

CHAPTER 3

HYPOTHESES AND THEORETICAL FRAMEWORK

3.1 McGuire's communication-persuasion matrix

McGuire's cognitive response formulation of message persuasiveness conceptualizes that there exist several possible outcomes of processing information from a message. Awareness, recall and attention, knowledge and comprehension, attitudes, information retention, purchase intent and behavior, are all important outcomes or "output variables" that measure advertising effectiveness.

Traditionally, in advertising research, consumers' attention and awareness represent initial stages of ad effectiveness (Lavidge and Steiner 1961). Being information-rich, it is difficult to imagine that DTC ads have much impact, if consumers do not pay attention to them (Menon et al. 2003). Knowledge and comprehension indicate the extent and nature of consumers' information processing from the ad. Knowledge may be determined by the learning and retention of the arguments presented in the message. Comprehension indicates an accurate understanding of the drug information in the ad.

Attitude development toward the advertising message is reflective of an affective state, according to McGuire's information processing framework. Consumers' attitudes towards an advertisement and brand have been widely acknowledged as mediators of

advertising effectiveness in the marketing and advertising literatures. From the perspective of a manufacturer, the ultimate goal of an advertising message is to induce the message recipient to behaviorally comply with the message advocacy. Accordingly, in most business-to-consumer marketing situations, purchase represents the desired outcome.

The "input variables" that possess valence for influencing ad effectiveness outcomes encompass characteristics related to the source, message, channel, receiver and destination of the communication (McGuire 1980). "Source characteristics" that influence persuasion include credibility, attractiveness and power. The "message characteristics" described in McGuire's communication matrix primarily consist of content, amount, style and organization of information, type of appeal used, and order and frequency of message exposure. "Channel variables" refer to the modality of message communication and its influence on communication effectiveness. "Receiver variables" have received widespread attention in literature as predictors of communication efficacy. These include audience characteristics such as demographics, ability and motivation to process information, passivity, susceptibility and personality. Lastly, destination variables encompass the desired consequence of communication and nature and timing of message communication.

Independent Variables: / Communication Component / Dependent Variables: / Steps in Being Persuaded	Source Variables	Message Variables	Channel Variables	Receiver Variables	Destination Variables
Message Presentation (p)					
Attention (a)					
Comprehension (c)		✓			
Yielding (y)		✓			
Retention (r)		✓			
Behavior (b)		✓			

Figure 1: McGuire's Persuasive Communications Matrix

The model of information processing is envisioned as a matrix comprising the input and output variables (McGuire 1980). Although it may be theorized that each category of input variables possesses the valence to exert an influence on consumers' information processing from DTC ads, the input variables under investigation in this study belong to the message category. The output variables that receive attention in this study comprise comprehension, yielding, retention and behavior.

Although attention is considered the primary step in information processing, it may be argued that consumers will not attend to the information in the brief summary unless they are able to read and process it. Therefore, we argue that it is essential to first assess factors influencing consumers processing of brief summary information prior to assessing attention. Determining the factors facilitating information processing from brief summaries may provide greater insights into how attention may be drawn to this information.

3.2 Study Hypotheses

It is becoming widely acknowledged that the existing format of brief summary in DTC ads (continuous prose format) is not complementary to lay consumers' information processing. Specifically, critics point to the "fine print" and the technical jargon that complicates message elaboration (Kaplar 1999; Menon et al. 2003; Sullivan 2003). In this study, we aimed to examine consumers' information processing after exposure to the brief summary, and explicate how multiple formats of the brief summary influence such processing. Determining the influence of format characteristics will help in optimization of brief summary design.

It may be argued that there are several ways in which the brief summary may be improved. This contention has received support from many observers of DTC advertising. Drawing from these opinions, as well as research in other product categories such as alcohol, tobacco and nutrients, we proposed to determine which attributes consumers desire in a brief summary using qualitative methods. A related objective was to determine the impact of risk information processing from the DTC ad on brand attitudes.

Therefore, the major research objectives of this study were:

(1) To assess how consumers' information processing differed across brief summary formats

(2) To determine the impact of information processing of risk information on brand attitudes

The hypotheses that emanate from these two objectives are discussed in further detail in the next section.

1. Consumers' processing of brief summary information

Prior research in DTC risk communication has been limited mostly to the risk information that is featured within the promotional copy. Specifically, research has focused on outcomes such as recall (Schommer, Doucette and Mehta 1998), knowledge, comprehension, retention, beliefs, evaluations and attitudes towards this information (Davis 1999; Morris Brinberg and Plimpton 1984; Sullivan 2001; Sullivan Schommer & Birdwell 1999) and preferences for formats of risk information presentation (Wogalter et al. 2002). There is very little known about how consumers process risk information from the brief summary. The brief summary is very different from the risk information on the promotional page because it is in much greater detail and is designed to present the full prescribing information.

Several researchers have argued that the brief summary does not add value to consumers' knowledge of product risks. According to this school of thought, the brief summary may be completely unnecessary, due to its complexity (Kaplar 1999). Nevertheless, an empirical investigation of how the brief summary influences consumer outcomes remains to be conducted. Among the major issues that need to be addressed are: Does the brief summary contribute to consumers' knowledge regarding the advertised drug? Does it influence the believability of the ad? Does it help elicit favorable attitudes towards the ad?

In order to explain consumers' information processing and derive empirically testable hypotheses, we draw upon the tenets of attribution theory. Attribution theory deals with how humans make causal attributions. It can be described as "causal explanations given for events by ordinary people" (Kelly and Michela 1980 p.460). Attribution theory is a well acknowledged hypothesis in consumer behavior that attempts to explain consumers' attributions of claims made by ads. Attribution theory posits that individuals attribute cause and effect based on covariance. That is, after exposure to an ad, the consumer may attribute the claims made in the ad (i.e. observed effect) to several underlying causes such as the advertiser's intentions to sell the brand and make profits or to the actual attributes of the brand (Settle and Golden 1974). If the consumer attributes the claims made in the ad primarily to the manufacturer's desire to sell and make profits, then the claim will be evaluated as less credible and this will in all likelihood decrease the probability that the consumer will make a purchase. Conversely, if attributions are made primarily to the attributes of the advertised product, then the claim will be more credible. In turn, this will increase the likelihood of purchase of the advertised brand.

Attribution theory finds widespread mention in the literature, especially in explaining the influence of a two-sided communication on several outcomes of ad effectiveness such as advertiser believability, ad believability, and attitude towards the ad. Two-sided advertising communications can be described as arguments in which both sides of an issue are presented. That is, an advertiser not only describes the positive attributes of the brand but also conveys, through disclaimers, the negative or

less efficacious nature of the advertised product on other attributes. This concept has also been referred to as affirmative disclosure in which "….. advertisers tell not only the positive story about their products, but also the salient negative side. Thus, in addition to any full disclosure of information about the product that might be required, advertisers would have to tell about product deficiencies and limitations" (King and Summers 1970 In Earl and Pride p.36). A DTC advertisement can be conceptualized as a two-sided communication wherein both positive and negative effects of the drug are described.

Attribution theory has received support from previous research in the context of two-sided communications. Settle and Golden (1974) reported a positive effect of employing two-sided messages on believability of the ad information and the credibility of the source. Golden and Alpert (1978) confirm this effect in mass transit advertising by reporting that consumers had better perceptions of believability after exposure to two-sided messages. These researchers also found similar results for the product class of deodorants (Golden and Alpert, 1987), that is, two-sided arguments led to better ad perceptions. Research in comparative advertising also demonstrates the superior effects of using two-sided messages on attitudes towards the advertisement (Etgar and Goodwin 1982) and ad believability (Swinyard 1981).

However, research by Earl and Pride (1980) in the context of OTC medications (Aspirin) demonstrates no significant difference across message-sidedness with respect to informativeness and retention. Belch (1981) also finds no significant differences between the effectiveness of one and two sided messages in comparative advertising.

However, the author (Belch 1981) theorizes that the ineffectiveness of their two-sided message may be attributable to the negative information being too "subtle". Studies that have found greater effectiveness for two-sided messages (Golden and Alpert 1987), prior to this study employed multiple disclaimers. Moreover, Belch (1981) examined message sidedness in TV ads whereas previous research examined print ads, which are undoubtedly processed differently than broadcast ads.

In the context of prescription drugs, research by Cady and Larson (1989) found that the brief summary had significant attribution effects on college students' perceptions of ad believability. Specifically, students exposed to ads that contained a brief summary found the overall ad to be more believable. This effect was demonstrated in an ad for an antidepressant. The attribution effects were demonstrated when the drug was indicated for the elderly, but failed to emerge when the indicated population was college students. However, Cady and Larson (1989) examined effectiveness only in terms of ad believability. Moreover, the population used in the study was a convenience sample of college students. Although the ad stimulus (ad for a drug indicated for depression) holds some degree of relevance for the study population, college students are not the primary market for depression drugs. Thus, the measurement of believability may have been biased by their use of this sample.

In the present study, we hypothesized that the brief summary would elicit similar attribution effects. We draw upon the research of Cady and Larson (1989) by assessing four separate constructs representing ad effectiveness i.e. evaluations of the quality of ad information, knowledge, ad believability, attitude towards the ad and brand and

intentions to use ad information in making decisions. Moreover, we attempt to control for the limitations in their study by examining an ad relevant to our target population. Since, ads with a brief summary not only convey drug benefits but also risks, they will be perceived as more believable and will generate favorable attitudes. We further hypothesized that consumers' knowledge regarding the advertised medication would increase and evaluations of risk information in the ad would be more favorable when exposed to an ad containing the brief summary as opposed to an ad without the brief summary. In sum, the following hypotheses proposed to demonstrate the positive effects of the brief summary on several effectiveness measures of information processing.

Objective 1a: To measure the effect of having a brief summary in DTC ads on consumers' information processing.

H_{1a1}: Consumers exposed to an ad with a brief summary have more favorable evaluations of the quality of risk information in the ad than those exposed to an ad without the brief summary.

H_{1a2}: Consumers exposed to an ad with a brief summary have more favorable evaluations of the quality of benefit information in the ad than those exposed to an ad without the brief summary.

H_{1a3}: Consumers exposed to an ad with a brief summary have higher knowledge scores than those exposed to an ad without the brief summary.

H_{1a4}: Consumers exposed to an ad with a brief summary have more favorable perceptions of ad believability than those exposed to an ad without the brief summary.

H_{1a5}: Consumers exposed to an ad with a brief summary have more favorable attitudes towards the ad than those exposed to an ad without the brief summary.

H_{1a6}: Consumers exposed to an ad with a brief summary have more favorable attitudes towards the brand than those exposed to an ad without the brief summary.

H_{1a7}: Consumers exposed to an ad with a brief summary are more likely to use the ad information in decision-making than those exposed to an ad without the brief summary.

Past research suggests that, for the most part, consumers are unable to focus on a warning label or risk disclosure to the extent that facilitates adequate processing of information. In this purpose, it is crucial that the design of risk information emphasize brevity. As discussed in the earlier section, the brief summary in DTC ads is often criticized for presenting consumers with too much information, using a small font size

and employing technical jargon, all of which makes it difficult for consumers to understand and use the information in their health care decision-making.

Perhaps, processing of risk and warning information in DTC ads may be enhanced by modifying the brief summary format. Incorporation of a summary of risks in a more user-friendly format may enable consumers to read and understand it more accurately and easily. It may be argued that simpler formats devoid of technical jargon may appeal to the entire spectrum of lay consumers. This assumes even greater significance in the context of prescription drugs, where the information disseminated is relatively more complicated than in other product categories. While it is easy to understand why a simpler brief summary would be more useful to consumers, there is still a lack of evidence about which format will assist consumers in understanding and using risk and warning information from DTC ads.

More recently, manufacturers have begun designing DTC ads that contain the brief summary information in a bulleted list format or a question-answer format in contrast to the continuous prose or paragraph format that is more widely used. Although it may be argued that consumers will prefer these modified formats over the continuous prose, little is known regarding how these formats of brief summary information will ultimately influence consumers' drug-related knowledge, their perception of ad believability and their overall attitude towards the ad and brand.

Sullivan (2002) examined three existing formats of brief summaries (continuous prose, bulleted list and the question-answer format) and found that consumers have better attitudes towards the question-answer format. However, the three formats of the

brief summary were based on three different drugs, and therefore not comparable. The amount, type and nature of information as well as characteristics of the advertised prescription drug (such as indication, name etc.) across formats need to be standardized to conduct a valid comparison of the influence of format on information processing. Preference of one brief summary over the other may have occurred simply as a function of the risks associated with a particular prescription drug. Moreover, Sullivan (2002) employed a student population to test information processing of ads for Lipitor® (for hyperlipidemia), Zocor® (for hyperlipidemia), and Avandia® (for Diabetes Mellitus), which are typically indicated for the elderly. This may introduce potential bias as the sample used for the study may perceive little relevance to the issue in the DTC ad.

Recently, the FDA published a draft guidance advocating the use of patient-friendly brief summary formats in print DTC ads. The guidance advocated the use of a "risk information window" that summarized the brief summary on the promotional page itself. In their guidance, the FDA invited research studies that empirically test the effectiveness of such a format. Further, the FDA also invited suggestions for alternative brief summary formats that would be congenial to consumers' information processing (FDA 2003). One such format was suggested by Roberts et al. (Roberts 2003) in their presentation to the FDA. This format of the brief summary was based on the nutrition label mandated on packaged foods. A nutrition facts panel based format has been suggested by several researchers in the past (Menon et al. 2003).

Thus, a related objective of this study was to test differences in information processing across the existing and proposed brief summary formats.

Objective 1b: To test differences in information processing across brief summary formats.

H_{1b1}: Consumers exposed to the newer (Bulleted list and question-answer formats) and recently proposed (Risk information window and nutrition label) brief summary formats have more favorable evaluations of the risk information in the ad than consumers exposed to the most commonly used brief summary format (continuous prose format).

H_{1b2}: Consumers exposed to the newer and recently proposed brief summary formats have more favorable evaluations of the quality of benefit information in the ad than consumers exposed to the most commonly used brief summary format.

H_{1b3}: Consumers exposed to the newer and recently proposed brief summary formats have more favorable evaluations of the quality of the brief summary in the ad than consumers exposed to the most commonly used brief summary format.

H_{1b4}: Consumers exposed to the newer and recently proposed brief summary formats have higher knowledge scores than consumers exposed to the most commonly used brief summary format.

H_{1b5}: Consumers exposed to the newer and recently proposed brief summary formats have more favorable perceptions of ad believability than consumers exposed to the most commonly used brief summary format.

H_{1b6}: Consumers exposed to the newer and recently proposed brief summary formats have more favorable attitudes towards the ad than consumers exposed to the most commonly used brief summary format.

H_{1b7}: Consumers exposed to the newer and recently proposed brief summary formats have more favorable attitudes towards the brand than consumers exposed to the most commonly used brief summary format.

H_{1b8}: Consumers exposed to the newer and recently proposed brief summary formats are more likely to use ad information in health care decision-making than consumers exposed to the most commonly used brief summary format.

2. Impact of information processing of risks on consumers' brand attitudes

Bettman (1979) classifies the goals of information provision in ads into two distinct sets; "processing goals" which deal with consumers evaluations, perceptions and processing of the information conveyed in the ad, and "policy goals" which are concerned with behavior or behavioral intentions. Here, evaluations of the ad

information, advertising believability and attitudes towards the ad are processing goals. We employed "intention to use ad information in health care decision-making" as a behavioral intention measure representing policy goals. Also, "attitudes towards the brand" was used as an effectiveness measure representing advertising goals. By employing two separate effectiveness measures, our study will have ramifications for manufacturers as well as policy-makers. Use of multiple constructs of ad effectiveness will provide a more comprehensive picture of the impact of risk information on brand attitudes. In explaining the effect of risk information on brand attitudes we tested competing models.

Proposed study model 1: Attributional effects

The most widely used format of the brief summary has attracted much criticism, primarily due to the small font size and technicality of the language. Descriptive research shows that consumers have less favorable evaluations of the risk information in DTC ads than the benefit information (Deshpande et al, 2004). Consumers may perceive that the manufacturers are deceiving them by conveying important risk and warning information in an incomprehensible manner. If the risk and side-effects were presented in a simpler, more user-friendly format, consumers may believe that manufacturers are making an attempt to educate and inform them about risks and hazards of taking the drug. In turn, this may enhance overall ad believability.

There is mixed evidence in the literature about the relationship between two-sided communications and brand attitudes. For example, studies using the attribution

theory framework have consistently demonstrated the impact of two-sided communication on ad believability and attitude towards the ad, its effect on brand attitudes and behavioral intentions has been debated. Kamins et al. (1989) found higher purchase intention scores for two-sided ads as compared to one-sided ads. Also, Etgar and Goodwin (1982) found higher intentions to buy the brand when two-sided persuasive appeals were used. However, Golden and Alpert (1978) find that a two-sided communication does not differ from a one-sided communication in its influence on behavioral intention.

Several studies in prescription drug risk communication have assessed the effectiveness of multiple risk information sources such as the PPI (patient package insert), PIL (patient information leaflets) and prescription package labels on patients' drug knowledge, beliefs and attitudes toward the information and ultimately their compliance with the prescription drug. One study reported that as many as three-fourths of the study sample found prescription drug risk information in pamphlets to be useful and would not negatively impact brand attitudes and use (Ferguson, Miller and Discenza 1987). These results led us to hypothesize that prescription drug warnings will not discourage consumers from using a product.

In model 1, we hypothesized that better perceptions of the risk information emanating from simpler brief summary formats would lead to more favorable attitudes towards the brand through the mediating effects of ad believability and attitude towards the ad.

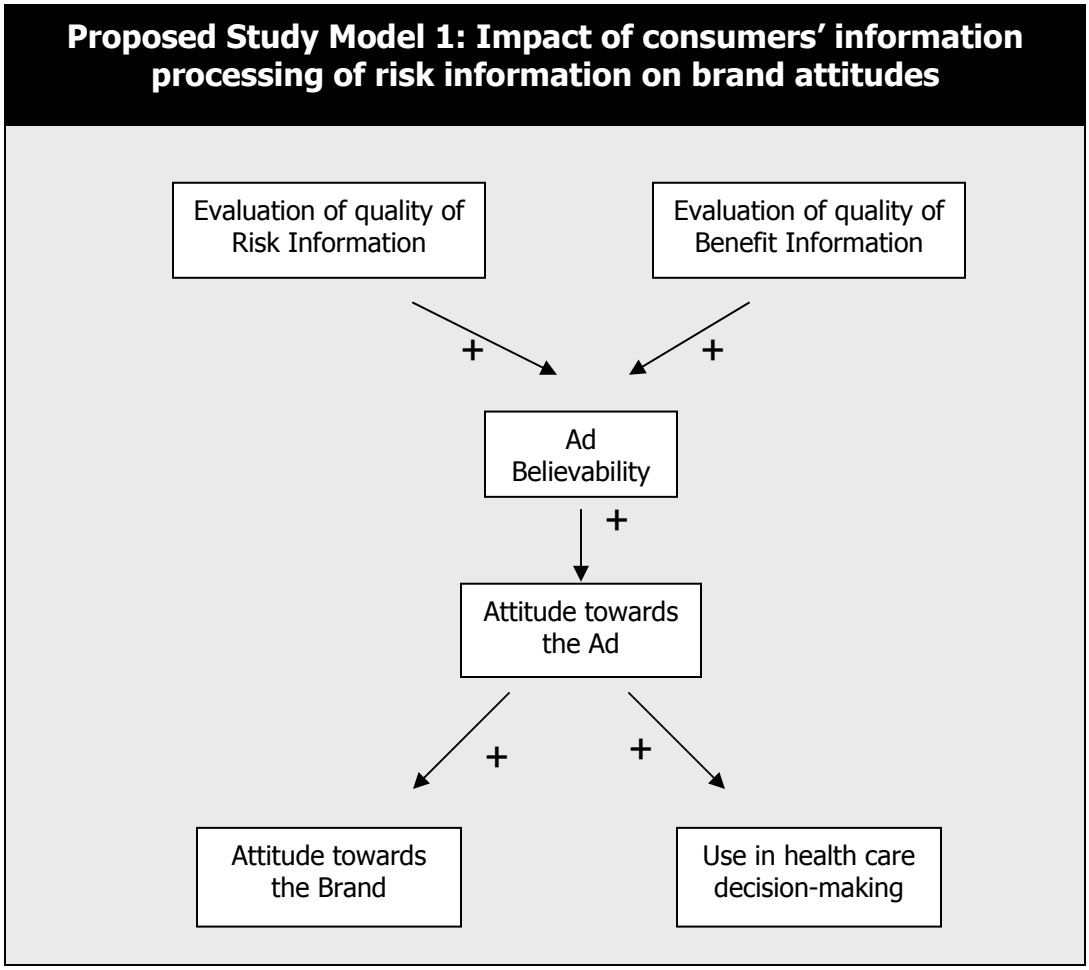


Figure 2: Proposed Study Model 1

Proposed study model 2: Effects of risk perception

Everett (1989) tested the Elaboration Likelihood model in prescription drug advertising and reported significant relationships between warning complexity, thought generation and perceived product risk. Lesser warning complexity caused increased elaboration and, in turn increased the perceived product risk. Subsequently, this led to negative brand attitudes. Although the effects of perceived risk on brand attitude towards the brand were demonstrated in both high and low knowledge consumers, the

effect of warning complexity on perceived risk (mediated by thought generation) was observed only among low knowledge readers. However, the risk information under investigation in Everett's study was limited to the promotional copy of the DTC ad. Morris, Ruffner & Klimberg (1985) reported that consumers had positive product evaluations when the risk information in the ad was less.

It may be argued that simpler brief summary formats will elicit better opinions of the risk information. There will be greater elaboration of the information and consequently greater knowledge of the product. In turn, this may increase the perception of the riskiness of the product and cause less favorable brand attitudes. The evidence in alcohol and tobacco advertising is complementary to this contention.

Thus, in model 2, we hypothesized that favorable perceptions of the risk information would lead to less favorable attitude towards the brand through the mediating influence of perceived product risk.

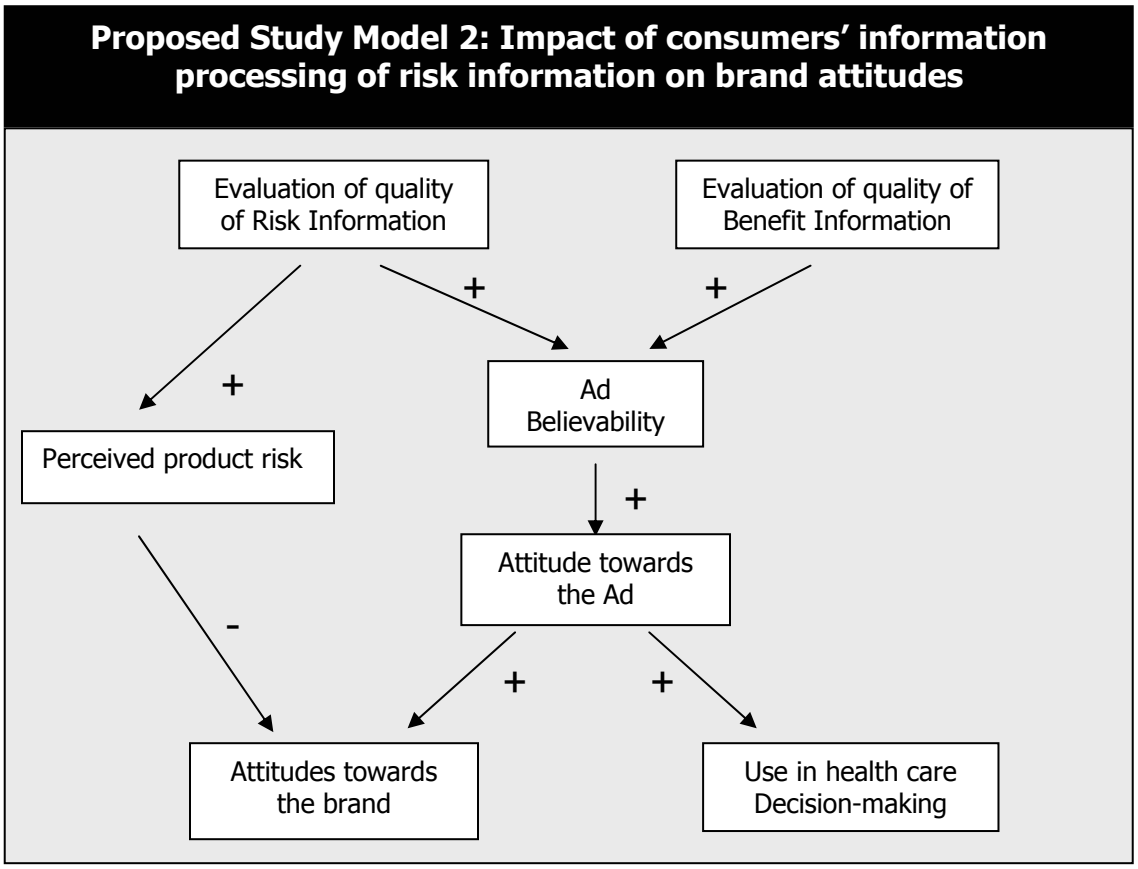


Figure 3: Proposed Study Model 2

The second objective of the current study was to test the proposed study models reflecting the relationship between consumers processing of the brief summary and brand attitudes. The hypotheses tested as part of the second study objective are listed below.

Objective 2: To test competing models delineating the influence of evaluation of quality of risk information in the ad on brand attitudes.

Proposed Study Model 1

H_{2a}: Evaluation of the quality of risk information in the ad positively influences perception of ad believability.

H_{2b}: Perception of ad believability positively influences attitude towards the ad.

H_{2c}: Attitude towards the ad positively influences brand attitudes.

Proposed Study Model 2

H_{2d}: Evaluation of the quality of risk information in the ad positively influences perceived product risk.

H_{2e}: Perceived product risk negatively influences brand attitudes.

CHAPTER 4

RESEARCH METHODOLOGY

The design and methodology of this study revolved around 2 main objectives: first, to assess how consumers' information processing differed across varying formats of the brief summary and second, to determine the impact of this information processing on brand attitudes. The following sections of this chapter describe the operationalization and measurement of study constructs, research design, and the data analysis.

This study involved dual components. First, a series of qualitative focus group interviews were conducted to gain a better understanding of consumer preferences for information in the brief summary. Subsequently, brief summary formats were designed based in part on the findings of the focus group interviews and these formats were tested among consumers using a monadic post-test only randomized experimental design, in which each study subject received 1 of six different formats of the brief summary that were developed by the researchers.

4.1 Qualitative Focus groups: Assessment of consumer preferences

This study utilized focus group interviews to gain in-depth insights into how consumers processed information in print DTC ads. Further, we elicited consumer preferences for presentation of risk information in the brief summary.

4.1.1 DTC ad stimulus

The DTC ad used in the study was a product-specific print ad for OrthoEvra®. Six different manipulations of the brief summary were developed. These were: 1) no brief summary (which served as the control group) 2) brief summary in the existing continuous prose format, 3) question-answer format 4) bulleted list format 5) risk information window format and 6) nutrition facts panel format. The control manipulation was used to assess if the brief summary in DTC ads was at all necessary. All manipulations to the brief summary were designed by the primary investigator in the study, and received input from a team of clinical pharmacists and health communication experts at the College of Pharmacy as well as social science analysts at the Food and Drug Administration Division of Drug Marketing Advertising and Communication (DDMAC), who are responsible for reviewing and regulating all DTC ads that are disseminated.

OrthoEvra® is administered via a delivery system that consumers are relatively less familiar with, especially in the context of prescription drug i.e. the transdermal route. Hence, we expected that the need for cognition for information regarding side-effects, benefits and mode of administration for OrthoEvra® will be higher than that for

most prescription drugs. Also, DTC advertising for contraceptive medications is relatively less common than for other therapeutic categories. The impact of ads in this drug class has received scant attention in the DTC advertising literature. Moreover, birth control drugs are relevant to a large proportion of the population, i.e. women. It has been reported that women are more involved with health care (Menon et al. 2003). Therefore, it may be argued that women may be more involved with the technical information regarding a drug that is relevant to them. The relevance of OrthoEvra® to a large population, the innovativeness of the drug product and the relative recency of the advertising campaign for this brand, all influenced the choice of the OrthoEvra® DTC ad as the stimulus in this study.

4.1.2 Study population

It is essential that the study population perceives the ad stimulus to be personally relevant. From this perspective, we believed that the ad for OrthoEvra® would be pertinent to females between the ages of 18-50 years. This population represented the target population for our study.

4.1.3 Research Method

Study participants were recruited by employing a convenience sampling technique. A snow-balling sampling method was used to recruit women representing the particular age spectrum, racial preferences and educational backgrounds. The focus groups were conducted at a conference facility at the College of Pharmacy. All

participants resided in and around the Athens metropolitan area (Athens, Commerce, Madison, Winder, and Atlanta).

The topic guide for these interviews was designed after input and feedback on potential discussion issues with faculty and staff members at the University of Georgia, College of Pharmacy, who represented both health care professionals and consumers. The focus group topic guide is provided in the Appendix of the manuscript.

The discussion during the focus group interviews was initiated following brief introductory remarks describing the study and investigators, and introductions by the participants themselves. Initially, discussion was initiated to elicit participants' general opinions about prescription drug advertising. This was followed by a discussion of issues that were central to the study objectives. Therefore, issues such as consumers' preferences for information that should be present in the brief summary, format of the brief summary information and potential changes to existing brief summary formats were discussed. Each focus group lasted about 90 minutes.

After each focus group interview, the discussion results were transcribed and an assessment was made of the issues that were subject to discussion. Key quotes were identified that summarized consumers' opinions of the varied issues discussed in the focus groups. Focus groups were discontinued upon discovery of redundancy in the responses of the participants.

4.2 Quantitative Experiment: Assessment of information processing

In addressing the study objectives, we used a randomized post-test only mall intercept research design. This involved the cross-sectional collection of data at 2 malls in the Atlanta metropolitan area. Subjects were exposed to the experimental stimulus and responded to measurement scales on a self-administered questionnaire. The study constructs and stimuli are operationally defined below.

4.2.1 DTC ad stimulus

The DTC ad used in the study was the same OrthoEvra® ad used in the focus groups. The six different manipulations of the brief summary were revised based on insights gathered from the focus groups. The resulting manipulations were: 1) no brief summary 2) brief summary in the existing continuous prose format, 3) question-answer format 4) bulleted list format 5) risk information window format and 6) nutrition facts panel format. The control manipulation was introduced in order to assess whether having the brief summary contributed at all to the effectiveness of a DTC ad.

Again, the promotional copy in all the manipulated versions of the ad stimulus was a replica of the original OrthoEvra® ad, except for the risk information window format. This format featured a brief summary window in the bottom 1/4th of the page called the risk information window. A back page brief summary was absent in this particular format. All ad stimuli used in the quantitative experiment are provided in the Appendix of this document.

4.2.2 Study population

As in the focus groups, the population used for the quantitative component represented the target population for the OrthoEvra® ad (women between 18 and 50 years of age). Pregnant women were not included in the study. Subjects were recruited from among shoppers at two malls in the Atlanta area.

4.2.3 Sample size estimation

To address the study objectives, we proposed to determine if significant differences existed between consumers exposed to the different manipulations of the brief summary with respect to their perceptions of ad believability, evaluations of ad information, drug-related knowledge and attitude towards the ad. For this purpose, we proposed to conduct one-way ANOVAs with each of the ad effectiveness outcomes representing a dependent variable. The independent variable had six levels, representing the six manipulations of the brief summary. For a one-way ANOVA with one factor and four levels, given a type I error rate (α) of 5%, a desired power of 80% and a moderate effect size of 0.25, SamplePower™ estimated that we would require 270 respondents (45 respondents for each manipulation) in our study sample to establish the validity of our statistical test (Cohen 1988). Path analysis was the analytical tool for testing the hypothesized relationships between constructs in the proposed study models. Kline (1998) suggests using a ratio of 5:1 of subjects to parameters for computing the minimum sample size. However, some others suggest using as much as 15 or 20 subjects per estimated parameter. For this purpose of this

study, we used a criterion of 15:1 ratio of subjects to parameters. The first study model comprised 11 parameters; the second study model comprised 14 parameters. Using the above criteria, we estimated a desired sample size of 210 subjects. Since the ANOVA required 270 subjects and the path analysis required 210 subjects, we used the higher of these two desired sample sizes as the effective sample size for the study.

4.2.4 Operationalization and Measurement

The objectives of this study focus on assessing consumers' information processing in response to the brief summary in a print DTC ad. The constructs measured in the quantitative component of the study were consumers' drug-related knowledge, evaluation of the quality of risk information in the ad, evaluation of the quality of benefit information in the ad, ad believability, attitude towards the ad, attitude towards the brand, intention to use the ad information in health care decision-making and perceived product risk. The operationalization and measurement of these constructs is explained below.

1) Consumers' knowledge of advertised drug

Consumers' knowledge of advertised drug was operationally defined here as the extent to which they are able to accurately comprehend the information about drug risks and drug benefits. For this purpose we developed and used a 12-item questionnaire, comprising of multiple choice questions, with equal number of questions pertaining to the risks and benefits of the advertised prescription medication. A "don't

know" response was included to discourage guessing. Such a true-false knowledge question test has been used previously to assess drug-related knowledge from DTC ads. (Morris 1984; Sullivan 1999). In the present study, an expert panel comprising clinical pharmacists was employed to generate the battery of questions. This battery was then tested for clarity and understandability in the pretests. The knowledge questions are presented in the survey questionnaire in the appendix.

2) Evaluation of the quality of risk information in the ad

AND

3) Evaluation of the quality of benefit information in the ad

Both these constructs represent variables that have not been subjected to comprehensive evaluations in prior research. Components of these constructs have however been measured previously. We developed scales to measure each of these constructs. For this purpose, we created an item pool by conducting a thorough search of the literature for items pertaining to the domains of these constructs. The item domain comprised constructs such as clarity, understandability, readability, completeness and accuracy. The generated items were then adapted for measuring consumers' evaluations of the risk and the benefit information in the ad stimulus. Prior to using these scales in the main study, we pretested them in a convenience sample of 30 subjects to assess the psychometric properties of the scale and to ensure clarity and comprehensibility of the measurement scale.

Evaluation of quality of ad information								
Readable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unreadable
Clear	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unclear
Complete	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Incomplete
Accurate	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Inaccurate
Informative	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not Informative
Understandable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not Understandable
Believable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unbelievable

4) Ad believability

We operationalized ad believability as the extent to which consumers perceive that the ad makes truthful and honest claims about the product. The risk communication literature in alcohol and tobacco advertising has often used believability as a measure of risk communication effectiveness. In this study, we used an ad believability scale developed by Beltramini (1982; 1985; 1988) to measure the believability of the DTC ad stimulus. This scale is a ten-item seven-point bipolar adjective semantic differential scale. The convergent and discriminant validity of the scale has been established in previous studies (Beltramini 1985). Moreover, the scale

has demonstrated high internal consistency reliability in previous studies (α ranges between 0.9-0.95) (Beltramini, 1985; 1988). The scale is described below.

Ad Believability Scale (Beltramini 1988)								
Believable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unbelievable
Trustworthy	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Untrustworthy
Convincing	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not convincing
Credible	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not credible
Reasonable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unreasonable
Honest	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Dishonest
Unquestionable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Questionable
Conclusive	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Inconclusive
Authentic	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not authentic
Likely	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unlikely

5) Attitude towards the ad

Attitude towards the ad is an important indicator of ad effectiveness and finds widespread application in advertising research. In this study, attitude toward the DTC ad was operationally defined as consumers' "predisposition to respond in a favorable or unfavorable manner" to a DTC advertisement (Mackenzie, Lutz and Belch 1986, p.130). In this study we used an attitude towards the ad scale developed by Mackenzie and Lutz (1989). The scale consists of three items measured on a 7-point bi-polar adjective semantic differential scale. This scale has been validated and has demonstrated adequate internal consistency (α=0.93) in previous applications. Moreover, due to the small number of items it represents a parsimonious measure of ad attitudes.

Attitude towards the ad (Mackenzie and Lutz 1989)								
Bad	1	2	3	4	5	6	7	Good
Unpleasant	1	2	3	4	5	6	7	Pleasant
Unfavorable	1	2	3	4	5	6	7	Favorable

6) Attitude towards the brand

The use of attitude towards the brand as an ad effectiveness outcome has been well supported in the marketing and advertising literature. In this study, we defined attitude towards the brand as a "predisposition to respond in a consistently favorable or unfavorable manner to a particular brand" (Ajzen and Fishbein 1980; Muehling and

Laczniak 1988). We used a scale developed by Muehling and Laczniak (1988) to measure this construct. It is a three-item seven-point semantic differential scale which has demonstrated adequate internal consistency reliability (α=0.95) in past research (Newell 1993). The scale is provided below.

Attitude towards the brand (Muehling and Laczniak 1988)								
Bad	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Good
Negative	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Positive
Unfavorable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Favorable

7) Intention to use ad information in health care decision-making

We operationally defined consumers' intentions to use the DTC ad information in health care decision-making as the consumers' assessment of the likelihood that s/he will use the ad information in talking to the doctor about the advertised brand or medical condition, or in specifically requesting the advertised drug from the physician. Currently there is no scale to measure this construct. Therefore, we adapted a scale developed by Mackenzie, Lutz and Belch (1986) to measure this construct. This is a three-item seven-point bipolar adjective semantic differential scale used previously to measure consumer intentions. This scale has shown adequate consistency reliability (α ranges from 0.88-0.95) (Shinde 2003). The scale is provided below.

Intention to use ad information in decision-making (adapted from Mackenzie, Lutz and Belch 1986)								
Likely	____ 1	____ 2	____ 3	____ 4	____ 5	____ 6	____ 7	Unlikely
Probable	____ 1	____ 2	____ 3	____ 4	____ 5	____ 6	____ 7	Improbable
Possible	____ 1	____ 2	____ 3	____ 4	____ 5	____ 6	____ 7	Impossible

8) Perceived Product Risk

Although validated scales exist in literature to measure ad effectiveness constructs, measurement of perceived product risk has not received much attention in the context of prescription drugs. Everett (1989) developed a "Perceived Risk" scale using 10 bipolar response items. An item reduction exercise was conducted and subsequent to 2 pre-tests the original scale was condensed to a 6-item version. This six-tem scale demonstrated good internal consistency (α=0.96) (Everett 1989). However, a content analysis of the scale items reveals that one of the items on the scale is actually a behavioral intention measure (How willing would you be to recommend Drug X to a friend?). We used a modified version of the scale developed by Everett (1989) to measure perceived product risk. The modified scale consisted five bipolar items measured on a 7-point semantic differential scale. The items are listed below.

Perceived Product Risk Scale (Everett 1989)								
1) How dangerous do you think drug X is for you?								
Very dangerous	____ 1	____ 2	____ 3	____ 4	____ 5	____ 6	____ 7	Not at all dangerous
2) How would you feel about using this drug yourself?								
Very afraid	____ 1	____ 2	____ 3	____ 4	____ 5	____ 6	____ 7	Not at all afraid
3) If you used this drug, how likely do you think you would be to suffer from Drug X's side effects?								
Very likely	____ 1	____ 2	____ 3	____ 4	____ 5	____ 6	____ 7	Not at all likely
4) How do you think the benefits of Drug X compare to the risks?								
Risks much greater	____ 1	____ 2	____ 3	____ 4	____ 5	____ 6	____ 7	Benefits much greater
5) How risky is it for you to use Drug X?								
Very risky	____ 1	____ 2	____ 3	____ 4	____ 5	____ 6	____ 7	Not at all risky

9) Covariates

Several other covariates such as demographics, health-related characteristics and variables related to past ad exposure were measured in this study. Consumers' age was measured using six categories (18-20 yrs, 21-25 yrs, 26-30 yrs, 31-35 yrs, 36-45 yrs, 46-50 yrs). Race was measured using categorical responses (Caucasian, American Indian or Alaskan native, Asian, Black or African-American, Hispanic or Latino, Native Hawaiian or other Pacific Islander and others). Educational level was also be categorically measured (Less than high school, High school graduate or equivalent, Associates/Technical/Vocational degree, Completed some part of college, College graduate and Graduate school or higher). Prior use of prescription medications for birth-

control was a dichotomous measure. Past use of birth-control options such as the pill, ring or patch were also dichotomous measures.

Consumers' prior exposure to print DTC ads was measured using a dichotomous item. Consumers' awareness of the brief summary and prior exposure to the brief summary were measured using dichotomous items. Further, the level of prior attention (glance at information, skim through information, read important information, and read all information) and frequency of prior attention (never, rarely, sometimes, often, and very often) to the brief summary were measured using categorical responses (Menon et al. 2003). Consumers' prior exposure to birth control DTC ads was also measured using dichotomous measures. Awareness of DTC ads like Yasmin®, Ortho-Tricyclen®, OrthoEvra® and Seasonale® was measured. Contracept was a fictitious drug included in this list as a check for false response.

Consumers frequency of magazine readership was measured categorically (never, once a month, once a week, 2-3 times a week, and greater than 3 times a week). Readership of specific magazines like Ladies Home Journal, Self, Cosmopolitan, Good Housekeeping and Prevention magazine were measured using dichotomous measures. The variable of interest here was consumers' readership of Self magazine, as the ad stimuli used in the study was being advertised in Self magazine at the time this study was being conducted.

Consumers' past behavior after exposure to DTC ads was measured using a dichotomous measure which indicated if they had ever asked their doctor for a prescription birth control medication after having seen a DTC ad. Acquiescence of the

doctor in response to this patient request was measured using a similar dichotomous measure.

4.2.5 Method

The design of the study was a post-test only experiment. Study participants were randomly assigned of one of six brief summary manipulations. Approval for the study will be obtained from the Institutional Review Board, Human subjects Office at the University of Georgia, Athens, GA (Project number: 2004-10653-1). Data were collected by personal interviews employing a structured questionnaire consisting primarily of closed-ended questions. Prior to the main study, we conducted a pre-test of the study questionnaire for testing the clarity, readability and reliability of the measurement scales. A sample of 30 respondents (≈ 10% of that needed for the main study) was used for the pretest interviews.

In the main study, the study participants were taken to an interviewing booth and requested to read the DTC ad assuming that it were for a prescription drug they were interested in taking. Time taken by the participant to read the promotional page was recorded in seconds. Four out of the six DTC ads had a back page brief summary. If the study participant did not read the brief summary, interviewers prompted them to do so and this was recorded on the study questionnaire. Time taken to read the brief summary was recorded separately where applicable.

After reading the DTC ad stimuli, consumers were interviewed using a paper-pencil technique. They were asked to provide responses to the measurement scales

that assessed their drug-related knowledge, cognitive and affective attitudes and behavioral intentions. The participants also responded to questions assessing demographic characteristics among other covariates. Data from the questionnaires were entered into a Microsoft Excel worksheet by one researcher and cross-checked by another analyst. After performing data checks, the data was exported into SPSS v11.5 for analysis. All relationships hypothesized in the path models were tested using LISREL v 8.53.

4.2.6 Analyses

The first objective of this study involved assessing how information processing differed across brief summary formats. Differences were assessed in terms of knowledge of the advertised drug, evaluation of quality of risk and benefit information, ad believability, attitude towards the ad and brand, perceived product risk and intention to use ad information in health care decision making. Hair et al. suggest that a MANOVA is an appropriate multivariate technique while testing differences between groups on several dependent measures that are correlated to each other (Hair et al. 1998). Also, MANOVA allows the researcher to control the "experimentwide Type I error rate" as a comparison is made across groups on a single vector of means (Hair et al. 1998). Accordingly, a multivariate analysis of variance (MANOVA) was conducted to determine if the outcome measures varied significantly across the treatment groups. If differences existed, we planned to use one-way analysis of variance (ANOVA) to test which outcome measures differed across the six brief summary manipulations. In order to

account for the inflation of alpha that may occur because of the several univariate ANOVAs run to test this objective, we applied the Bonferroni adjustment while interpreting p-values (Hair et al. 1998). If differences did exist on any effectiveness measure, post-hoc multiple comparisons using a conservative Scheffe's test, were used to test which specific formats differ significantly in terms of the effectiveness measure.

The second objective of the study was to determine the effect of evaluations of quality of risk information on brand attitudes and to identify the specific mediators of this effect. Path analysis was used to test the relationships proposed in the competing models.

Path analysis is a method of simultaneously analyzing multiple relationships between several observed variables. These observed variables may be either exogenous or endogenous. An "exogenous" variable is defined as a predictor or independent variable represented by X, whereas an "endogenous" variable is a criterion or dependent variable represented by Y. The concept of path analysis is an extension of multiple regression, in that it can handle multiple endogenous variables.

Typically, the researchers specify a structural model representing relationships among the exogenous and endogenous variables. Every endogenous variable is associated with a "disturbance", denoted as D, which represents the unexplained variance in the endogenous variable after taking into account the prediction by the exogenous and other endogenous variables. The estimation of a path model requires the specification of several matrices. These matrices are represented in a functional equation as:

$$\mathbf{Y = BY + \Gamma X + \zeta}$$

A description of these matrices and the assumptions of path analysis are provided in the tables below.

Table 1: Matrices involved in Path Analysis

Matrices in Path Analysis	Matrix Form	Matrix Description
Y	(NY x 1) column vector	exogenous or independent variables
X	(NX x 1) column vector	endogenous or dependent variables
ζ (Zeta)	(NY x 1) column vector	error terms or disturbances associated with the endogenous variables
B (Beta)	(NY x NY) matrix	Structural relationships between endogenous variables
Γ (Gamma)	(NX x NY) matrix	Structural relationships between exogenous variables and endogenous variables
Φ (Phi)	(NX x NX) matrix	Variances and covariances of exogenous variables
Ψ (Psi)	(NY x NY) matrix	Variances and covariances of ζs i.e. error terms or disturbances associated with endogenous variables

Table 2: Assumptions of Path Analysis

Assumptions of path analysis (Mueller 1996)
1) The endogenous and exogenous variables are measured with negligible error.
2) Both the endogenous and exogenous variables expressed as deviation scores have a mean of zero i.e. E(X) = E(y) = 0.
3) The disturbances associated with the endogenous variables have a mean of zero and are homoscedastic i.e. $E(D_i) = 0$ and variance of D_i is constant across all observations.
4) The disturbances associated with the endogenous variables are uncorrelated with the exogenous variables which is represented as E(XD') = E(DX') = 0
5) The disturbances associated with the endogenous variables are uncorrelated with each other i.e. all off-diagonal elements of the variance/covariance matrix of D_is are zero.
6) All hypothesized relationships between the exogenous and endogenous variables are assumed to be linear in nature

Table 3: Stages in Path Analysis

Stage	Description
1	Developing a theoretically based model
2	Constructing a path diagram of causal relationships
3	Converting the path diagram into a set of structural equations
4	Choosing the input matrix type and estimating the proposed model
5	Assessing the identification of the structural model
6	Evaluating goodness-of-fit criteria
7	Interpreting and modifying model, if theoretically justified

Hair et al. (1998) specify seven stages in conducting a path analysis. These seven steps are summarized below in table 3 and discussed in separate sections.

Stage 1: Developing a theory-based model

We tested two theoretical models that were specified apriori. The first theoretical model that was tested in this study was based on an application of attribution theory in testing effectiveness of two-sided advertising. We hypothesized that consumers' evaluations of the risk information in the ad would drive their perceptions of ad believability. In turn, this would influence their attitude towards the ad and the advertised brand. In the alternate model we hypothesized, that positive evaluations of the risk information in the ad would increase perceived product risk. In turn, this would influence brand attitudes. The two models discussed above were empirically tested to determine which model fit the data better.

Stage 2: Constructing a path diagram of causal relationships

The theoretical models that were tested in the path analysis are represented schematically as path models in the following figure.

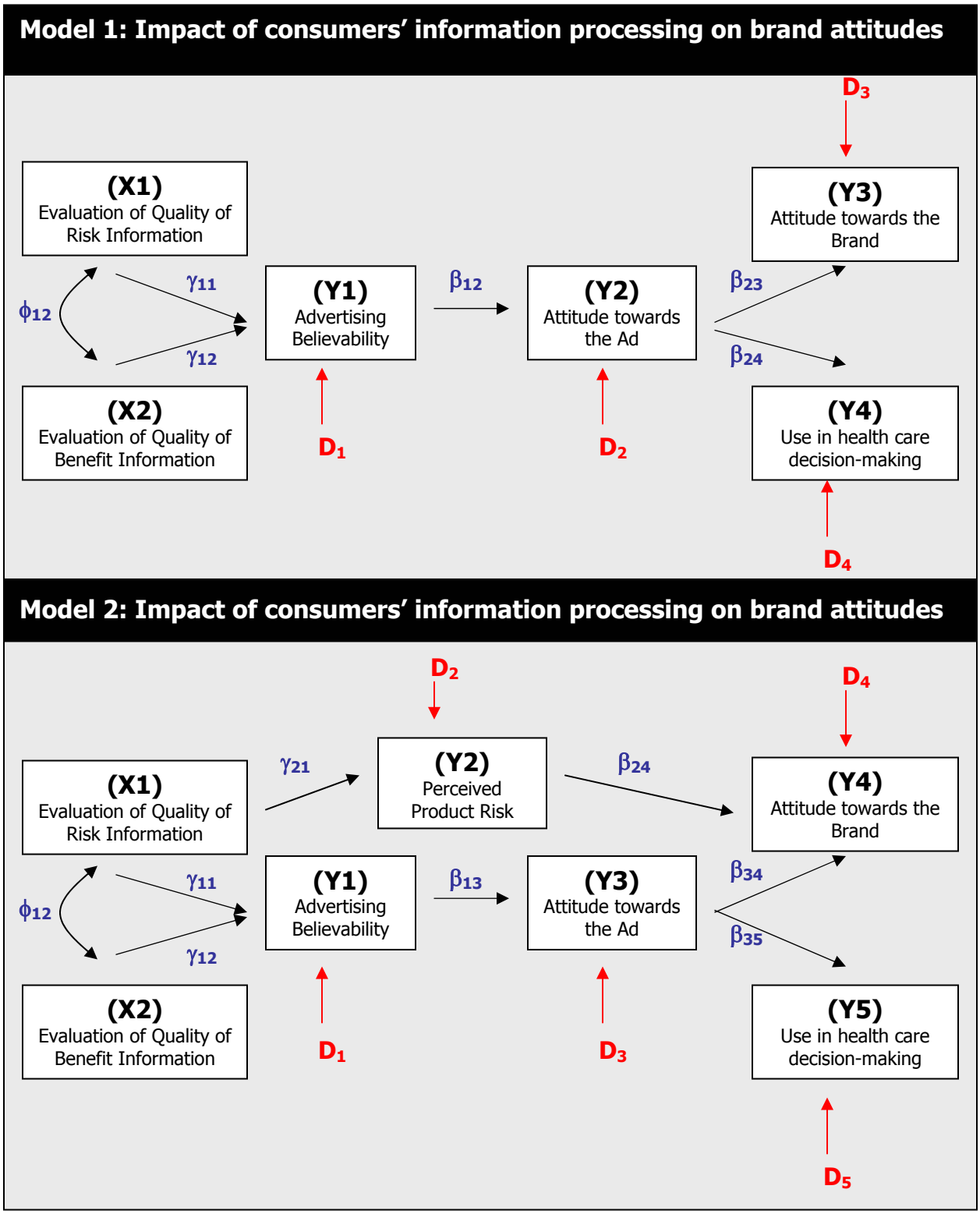


Figure 4: Path Analytic Models

The constructs in the path diagram are the observed variables which are typically represented within rectangles. The second element of a path diagram is the arrow. One-headed arrows signify direct causal relationships, Direct effects between the observed variables are represented by $\rightarrow$. Feedback relationships or loops are represented by $\leftrightarrows$. Path analysis allows specification of non-causal relationships, i.e. two observed variables in the model are hypothesized to covary but the causal relationship or direction is unknown. Double-headed curved arrows $\leftrightarrow$ signify such relationships. The absence of an arrow between two observed variables indicates that there are no causal relationships between the variables. The strength of the relationships between the observed variables are indicated by path coefficients. Relationships between the endogenous variables are represented by β, whereas relationships between the exogenous and endogenous variables are represented by γ.

Stage 3: Converting the path diagram into a set of structural equations

The path model in the above figure can also be represented in the form of structural equations describing relationships among the observed variables.

Table 4: Structural Equations for Path Analytic Models

Equations for Model 1
$Y_1 = \gamma_{11} X_1 + \gamma_{12} X_2 + D_1$ $Y_2 = \beta_{12} Y_1 + D_2$ $Y_3 = \beta_{23} Y_2 + D_3$ $Y_4 = \beta_{24} Y_2 + D_4$
Equations for Model 2
$Y_1 = \gamma_{11} X_1 + \gamma_{12} X_2 + D_1$ $Y_2 = \gamma_{21} X_1 + D_2$ $Y_3 = \beta_{13} Y_1 + D_3$ $Y_4 = \beta_{34} Y_3 + \beta_{24} Y_5 + D_4$ $Y_5 = \beta_{35} Y_2 + D_5$

Stage 4: Choosing the input matrix type and estimating the proposed model

Path analysis typically uses either the covariance matrix or the correlation matrix as the input data. Although raw data can be input, the path analysis procedure converts the dataset into one of these two matrices prior to estimation procedure. The covariance matrix allows a comparison of models in different populations and is a preferred form of input data. The model can be estimated using either the maximum likelihood estimation or an ordinary least squares (OLS) approach. The maximum likelihood procedure is reported to be more efficient and unbiased as compared to the OLS estimation, especially when the normality assumption is met (Hair et al. 1998). Accordingly, data were specified in the form of a covariance matrix and the path analytic model was estimated using the maximum likelihood procedure.

Stage 5: Assessing the identification of the structural model

The "observations" in a path analytic model refer to the number of unique known quantities. This is computed as:

$$\textbf{Number of observations} = \frac{v\,(v+1)}{2}$$

Here, v is the number of observed variables, which is the sum of the number of exogenous and endogenous variables. The number of parameters in a model is the "Total number of variances and covariances (i.e., unanalyzed associations) of exogenous variables that are either observed or unmeasured (i.e., disturbances) and direct effects on endogenous variables from other observed variables" (Kline 1998, pg 104). A model is "under-identified" when the number of parameters exceeds the number of observation. A model is "over-identified" when the number of observations exceeds the number of parameters. A "just-identified model" has equal number of observations and parameters. Empirical identification (i.e. an over-identified or just-identified model) is a necessary condition for model estimation.

In the first model, the number of observations was 21 and the number of parameters was 12. In the second model, the number of observations was 28 and the number of parameters was 15. In both models, the number of observations were greater than the number of parameters estimated; the models were over-identified and satisfied the identification condition.

Stage 6: Evaluating goodness-of-fit criteria

The model was initially examined for "offending estimates". Offending estimates are defined as coefficients that exceed theoretical limits. The most common occurrences of these estimates include (1) Heywood cases or negative error variances (2) coefficients with large standard errors and (3) standardized estimates of coefficients exceeding the value of 1.0. A rule of thumb used in path analysis is that the modification indices of any path should not exceed 100. No modification indices in either models exceeded 100.

After examining for offending estimates, model goodness-of-fit were examined. There are 3 types of goodness of fit indices; (1) absolute fit indices (2) Incremental fit indices (3) parsimonious fit indices. Absolute fit indices evaluate the fit of the specified model to the variance-covariance matrix of the observed variable. Examples of absolute fit indices include chi-square goodness of fit test, Good-ness of fit index (GFI), Root Mean Square Residual (RMSR) and Root mean square of approximation (RMSEA). Incremental fit index measures compare the fit of the model to a null model comprised of a one-factor single construct model with zero measurement error. Examples of incremental fit measures include Adjusted GFI, Tucker-Lewis Index (TLI) and Normed Fit Index (NFI). Parsimonious fit indices compare the goodness-of fit to the number of coefficients estimated to obtain the fit i.e. these measures penalize models with large number of estimated coefficients. Examples of these measures include parsimonious NFI and parsimonious GFI.

The acceptable values of the goodness-of-fit measures are described in the following table.

Table 5: Goodness-of-Fit Measures in Path Analysis

Goodness of fit measure		Accepted values
Absolute Fit Indices	Chi-square statistic	pvalue>0.05
	Goodness of fit index (GFI)	> 0.9
	Root Mean Square Residual (RMSR)	< 0.08
	Root Mean square of Approximation (RMSEA)	< 0.08
Incremental Fit Measures	Adjusted Goodness of fit index (aGFI)	> 0.9
	Normed Fit Index (NFI)	> 0.9
	Tucker-Lewis Index/Non-Normed Fit Index (nNFI)	> 0.9
Parsimonious Fit Index	Parsimonious Normed Fit Index (pNFI)	Not applicable*
	Parsimonious Goodness of fit index (GFI)	Not applicable*

* Used to compare between models. Higher value indicates better fit.
Note: Table Adapted from Hair et al. 1998.

Stage 7: Interpreting and modifying model, if theoretically justified

The competing models were compared using the chi-square test of difference and modification indices. The path coefficients were examined for significance and

directionality to test *a priori* hypotheses that specified relationships between the study constructs.

CHAPTER 5

RESULTS

5.1 Qualitative Phase

The qualitative component of this research involved focus group interviews with subjects who were representative of the target population. Accordingly, three such interviews were designed and implemented with 25 female consumers in the 18-50 year age range, with each interview comprising of 8-9 participants. A summary of the focus group discussions is provided below.

Consumers' opinions about DTC advertising

All focus group participants reported having seen and read at least one DTC ad previously. Overall, participants believed that DTC ads were simply a marketing gimmick employed by the drug industry. Nevertheless, it was clear that they had favorable opinions of the manifold benefits of drug advertising such as increasing consumer disease awareness and drug knowledge. Still, the consensus weighed heavily towards the opinion that the drug industry was advertising its products with an explicitly financial motive. For example, one participant mentioned:

"…. So they show people having a good time, running, skipping, its sunny, people smiling, holding hands. Well, life is better on drugs right!".

A common theme during the focus groups revolved around the effect of prescription drug ads. Participants were particularly concerned that drug ads may "create" a need for prescription remedies rather than fulfill it. Perhaps, these ads could be so compelling as to convince people who do not suffer from the illness to believe that they may actually be symptomatic or would soon be so. For example, one participant stated:

"Sometimes you see these commercials and say Oh my gosh, I have 9 out of the 10 symptoms they are talking about. I have the disease. I should speed-dial my doctor. I think it gets people hyper-aware. I think people overdo it".

Despite this concern, participants reported being encouraged by the statement in DTC ads exhorting consumers to talk to their doctor about the appropriateness of the medication.

Regarding the advantages of DTC advertising, focus group participants demonstrated a recognition that such ads could help alleviate the stigma associated with certain diseases such as anxiety disorders, depression and erectile dysfunction. It was felt that ads for drugs, that treat such conditions, could draw many more consumers to seek therapy. In such cases, prescription drug advertising may be appropriate as the benefits justify the time and money spent on such advertising efforts. In this regard, one participant remarked:

"If someone else has these social anxiety disorders, then they won't feel as self conscious saying that to their doctor. Other people on TV have these disorders, so they

can tell their doctor they are having the same problems, which might make them feel not so odd".

Among the variety of drug advertisements that qualify as DTC ads, participants in the focus group exhibited a particular dislike towards "reminder ads" (ads that only mention the name of the drug and a statement asking consumers to talk to the doctor about that drug, but not the condition that it is indicated to treat). Clearly, these ads seemed to confuse and mislead consumers. They perceived these ads as glossing over certain parts of drug information that may show the product in a negative light. Such ads made consumers wary of the product and suspicious of other DTC ads. The negative attitudes towards such ads were made clear by one participant:

"Half the time you don't necessarily know what product it is going to be for, especially lately with all the athletes, with all the profession football coaches … hey here's this new drug and this coach uses it … and I am wondering here what that drug even treats".

During the discussion regarding general attitudes towards DTC ads, participants were emphatic about the clearer and more interactive nature of DTC ads on TV. They seemed more amenable to attending to such ads rather than flip the channel, owing to the catchy narrative and audio-visual appeal. Certainly, print ads may not be as effective in stimulating affective attitudes because of the lack of attention-grabbing imagery and persona. In fact, as one participant remarked, print ads did not convey the same feeling as the TV ads she had seen previously and seemed somewhat incomplete.

"I think it's [print advertising] *not as effective as TV ads, especially when you are trying to market, she looks like she is happy, but she is not skipping, hopping, jumping, it's not like it's a full commercial".*

Surprisingly though, when the focus group discussion gravitated towards the issue of side effects and risks, most participants reported being apprehensive of seeing and listening to such information in TV DTC ads. The seemingly endless list of side effects, warnings and contraindications implied to viewers that the product was very risky. In addition, the narrative, imagery and music seemed to mask the risk and warning information in the background. Perceptions towards this aspect of TV ads were amplified by the following remark:

"A lot of the time when I am watching TV and I see pharmaceutical ads on, they run through the side effects so quick and you really are not paying any attention. You miss them because you zone out and you are still watching the hopping, skipping jumping happy. Unless maybe for the obesity drugs, the side-effects are really unpleasant, you say …. What! Do you really want to take this drug! Why?"

The mixed views about the DTC ads on TV transferred to the domain of print ads. While they were considered not nearly as creative as their counterparts on TV, print DTC ads seemed to elicit favorable opinions on in informativeness. Particularly for drugs that were personally relevant, focus group participants seemed to concur that print ads allowed them to absorb information at their own pace and offered specific information that could be used when talking with the doctor. One of the participants in the focus group remarked:

"The reason I like print ads you are able to get more detailed information. That I think is the biggest benefit of having print ads".

Opinions about quality of information in DTC ads

Participants believed that DTC ads generally conveyed the benefits of the prescription drug in a clear and understandable manner. Most consumers agreed that the ad stimulus that they received during the interview (the OrthoEvra® ad) also effectively conveyed information about the benefits of the drug. While participants clearly agreed that health care professionals, especially physicians, remained the most reliable and competent source of drug information, they reported that DTC ads were effective in educating consumers about the benefits of the prescription drug. As one participant put it,

"I think it's [the OrthoEvra® ad] *pretty straightforward at telling you that. I think the actual size and the actual thinness of the drug shown here is pretty effective because otherwise people will think, Oh! It's probably like a big bandaid, and it's clearly not". I mean I would obviously still talk to a doctor about it, but for what I want for now I think it does a good job".*

When the discussion reached the core issue of opinions towards the risk information conveyed in the ad, specifically the brief summary, participants clearly were overwhelmed by the sheer amount of information in the brief summary. Consumers thought that the current brief summary was overwhelming & intimidating. It was clear that most consumers realized that there was a page at the back of the ad copy with

technical drug information, but chose to ignore it. When asked for the reason behind ignoring this page altogether, a participant commented:

"The back is definitely a little overwhelming, and I have seen a few of them. When I get to that I always say Oh my gosh! That part again! I don't think I would take the time to read it". I think its so much information that it's overwhelming".

"I think whatever is in the [warning] *box, maybe I would read that part. I don't think most consumers would sit and read this everyday". "They can be very interested and still not read anything after the main page".*

Participants identified the following issues as problematic in processing the information in the brief summary:

1) Small font size,

2) Amount of information and,

3) The complexity of the information.

The amount of white space in the brief summary (or the lack of it) was also mentioned as a minor concern.

"It's way too small. It makes me sick and cynical. It makes me wonder what they are trying to say. What are they really saying here? Why should I spend my time reading this?"

Despite ignoring it, participants were unanimous in voicing their opposition against removing the brief summary from print DTC ads altogether. It seemed that the absence of such information would almost make the drug seem less safe, or trivialize

the information. Still, participants were equally unequivocal in demanding that the presentation of the information be more consumer-friendly.

"I think that this information is necessary. If it were simpler, I would definitely like that. Then I would know what I am getting myself into". "No, that [removing the brief summary] *is not acceptable. As a society we know there should be more information".*

Subsequent to examining the different brief summary formats that were developed by the investigator, the question-answer format seemed to be the undisputed choice of most the participants. The question-answer format mimicked the questions that would generally arise at a doctor-patient consultation. Furthermore, this format seemed to provide a list of frequently asked questions (FAQ) – a format with which most consumers are familiar. Moreover, the arrangement of the brief summary facilitated comprehension and easier access to relevant information.

"The questions here are actually the questions inside my head when I look at such an ad. It's very easy to follow along and you don't realize how much information there is. Each question is a new topic. You just go through it and don't realize that a lot of information is being given to you. It's easy to skip over the questions that don't relate to you. I don't have to read the whole section. Like the section with the 16 years of age. I know that that portion is not relevant to me".

The bullet-point format is another newer brief summary version that has been increasingly used by advertisers. Reactions to this format were less favorable than towards the Q&A format. Apparently, the bulleted list format was perceived as more

clinical, although it contained exactly the same amount of information, in the same language. Perhaps, the bulleted list seemed to offer no clear informational advantage over the existing continuous prose format, other than facilitating clarity of presentation.

"*I think it* [bulleted list format] *steps over to looking more clinical. Most people talk in a question answer kind of way, especially with their doctors. This* [question answer format] *also gives you an idea about the kind of questions you could ask. This one* [bulleted list format] *just goes on … what kind of question would I have?"*

A brief summary format that has been recently proposed but has not yet been widely used is the risk information window. This window has been proposed to appear on the ad copy and provide a brief summary of the risk and side effect information that is in addition to the major risk statement that already appears on the front page of the ad. Focus group participants did not like the initial risk information window format that was developed by the investigator. This version had the risk information in a box having a white background. This risk information window was superimposed on the promotional page of the age and clearly stood in stark contrast against the ad copy. The negative reaction against this version was clearly evidenced by the following observations by participants:

"O my gosh! Oh no! I don't think it's good. It's just sort of in your face, Oh, Oh, Hey, Read me. It looks like an afterthought. It makes me think like something bad must've happened to people who took this".

"*They were forced to put a big warning on their ads, like cigarette packets -May cause cancer. Another thing with this format is that the side-effect information caught*

my attention first and those things are very impressive. I won't take this drug because of that. It's just like a black-box. Even if I weren't interested in this drug I would be like - man! What is this stuff! I am going to read this stuff, because it's just so out there. It would definitely attract attention, maybe too much".

Since the contrast of the initial risk information window format elicited such negative reactions from consumers, an alternative version of the format was developed in which the information was blended into the ad copy more subtly. This simple change in the appearance of the risk information window, without any modification to the information presented, led to a drastic improvement in participants' reactions to this format.

Recently, risk communication pundits have proposed that drug risks and side effects be communicated in drug ads in a manner that resembles the nutrition facts panel on food labels. Accordingly, a format that closely resembled the nutrition facts panel was developed and tested with the focus group participants. Consumers had mixed opinions about this format. Despite being succinct, the format was perceived as "short-changing" the consumer. Specifically, participants clearly believed that food and drug products were different entities. As such, they perceived that using food-product type labels on drug ads would trivialize the side effect and risk information. Accordingly, the format was almost unpalatable to consumers.

"This is something like you would find on food products. I like it on food products. It's not inviting enough here. I think you can read it quickly, skim on down, the way it is".

Once they had completed discussing opinions about each of the formats individually, participants were asked to rank these formats in decreasing order of preference. The following order emerged from this exercise –

Table 6: Consumers' Preferences for Brief Summary Formats

Consumer preferences for brief summary formats
1. Q&A format
2. Blended final risk information window
3. Bulleted list format
4. Nutritional label format
5. Initial risk information window
6. Original continuous prose format
7. No brief summary format

Although, the newer versions of the brief summary seemed to be preferred to the existing format (continuous prose), it was also clear that consumers desired the provision of some risk information to none at all.

Redesigning of the brief summary formats

The initial draft versions of the brief summary formats, which were used in the focus groups, were redesigned after input from the focus group participants. The following issues were considered while redesigning these formats

Ordering of the information

We asked consumers in the focus groups to rank each piece of information that is found in the brief summary (e.g. effectiveness, uses, caution etc.) from 1 to 9 in the order they would like it to appear. Almost all consumers wanted the effectiveness information to be listed first in the brief summary followed by risk information. The following sections of information are listed in the order that consumers preferred to see them in the brief summary.

Table 7: Consumers' Preferences for Sections in the Brief Summary

Ordering of sections in the brief summary
1. Active Ingredients
2. Effectiveness
3. Indications and Uses
4. Caution statements
5. Common side-effects and adverse drug reactions
6. Risks
7. Warnings
8. Precautions
9. Overdosage information

Use of additional information sources

DTC ads are mandated to provide consumers with additional sources of information about the advertised drug. Among these sources of "adequate provision" are 1) Internet websites, 2) Toll-free numbers 3) a print media source of comparable dissemination and 4) a statement encouraging consumers to visit their health care professional for more information. In the ad stimuli that were presented to the focus group participants, the Internet emerged as a prominent source of adequate provision. Specifically, consumers desired that such information be provided on the brief summary page also. Most participants demonstrated a clear dislike for using the toll-free number. A lack of anonymity and an apprehension of being sold the drug were among the prominent complaints that participants reported having with the toll-free number.

"I would never call toll-free number to ask about the drug, never, I promise I wouldn't. If you call the toll-free number, I feel that the people will try to sell you something about the drug. If you go to the website, no one is going to bother you. Websites have all the information … whereas on the phone, you would always wonder what they are not telling me. But on the website, you can see, obviously its all there".

"Like if you said, at the toll free number I would reach a pharmacist, then I would call. Otherwise, if they are giving someone $5 to $6 an hour to answer my question, they are not going to know the answers to my questions".

Font size and type

A major criticism of the existing continuous prose format concerns its font size and type. Focus group participants were shown several examples of the question answer format in font sizes ranging from a 4-point font to a 12-point font. This exercise revealed that an 8-point font size was preferred, followed by the nine-point font size. A font size of 10 points was perceived to be too prominent or "in your face". Simpler and block font types such as Arial, Tahoma and MS Serif were preferred to boldface or artistic-type designer fonts such as Brush script, Comic sans, Stencil or Arial Black.

Effective use of white space

A minor concern with the brief summary that participants expressed at the beginning of the focus group concerned the lack of white space in the existing brief summary. Participants were then shown the question answer format with white spaces between the sections of risk and side effect information and white space at the end of the page. Participants desired formats that had white space at the end of the page rather than between sections of risk and warning information. The white space at the end seemed to indicate a clear finishing point for the brief summary. However, when the white space was spread out throughout the brief summary between sections and paragraphs or bullet points, consumers perceived that there was an overload of information in the brief summary. As a result, they felt less inclined to read the information.

"I like the space at end, because you know it's over when you see the space. Yeah because when it's spread out it looks like too much information".

Colors, borders etc.

The use of colors, borders, highlights, shading etc. was not perceived to be very important in communicating risk and side effect information. In fact, a majority of participants expressed concerns about being distracted from the seriousness of the information by such executional elements. Consumers liked the black and white formats better, as these formats seemed to indicate that the information was serious and important. The black and white page looked more like a health-related article in a magazine, rather than an advertisement to them. Most consumers agreed that they would be more likely to read the information if it was in simple black and white type. However, participants did suggest that the use of colors such as red or orange could be used to highlight the certain sections of information, thereby facilitating the location of the most important information.

"Making colorful would distract. I like the white part. Unless you were to put highlights in red or something, to have some important information pop. I don't think any color change would help".

Endorsers used in the ads

To determine if other executional cues would affect consumer information processing from the ad, the focus group discussion extended to the issue of consumer

response to endorsers. Most consumers seemed to dislike the practice of using celebrities in prescription drug ads. Although they thought celebrities were credible in commercials for cosmetics and other consumer goods, they perceived celebrities as being inappropriate endorsers for prescription drugs. In fact, some consumers mentioned that they would distrust any prescription drug ads that featured celebrity endorsers. An interesting comment made by several participants concerned the differential impact of celebrities across the gender of the audience.

"I wouldn't want a celebrity. I would think less of it. Like why do they have to use a celebrity to sell their drug? I don't think necessarily that it would make me want to use that drug more…. Yeah personally I think it works more for men than women."

Consumers did not express any particular preference for an endorser according to racial background. However, they expressed that the age of the endorser would lead them to think more about the appropriateness of the advertised drug.

"I would respond equally to the ad if it were a minority you know. Now if it were an older woman, I might react differently".

5.2 Quantitative Phase

The quantitative component of the study involved administering the ad stimuli (same ad copy but different brief summary formats) and conducting personal interviews with consumers who were representative of the target population for birth control products (females between the ages of 18-50 years). These consumers were asked to

respond to a structured closed-ended questionnaire consisting of rating scales measuring the constructs of interest.

5.2.1 Pretests

In order to ensure the measures that we used were in fact, reliable, and that the questionnaire was understandable and clear to the respondents, we conducted pretests of the questionnaire. Using the mall-intercept survey technique at two Atlanta area malls, 30 consumers were randomly assigned to the 6 different versions of the ad stimulus (different brief summary formats). Internal consistency reliability measures were computed for the rating scales that were used in the study. This exercise revealed that all our measures demonstrated acceptable levels of Cronbach's alpha internal consistency (ranging from 0.87 to 0.95). All items on each of the different scales exhibited high item-total and inter-item correlations. Moreover, removal of any single item from any of the scales, did not lead to a substantial increase in the internal consistency.

Anecdotal evidence showed that respondents did not face any issues in understanding the instructions in the questionnaire or in providing answers to any of the rating scales. On average, respondents took about 15 minutes to complete the entire exercise (reading the ad and completing the questionnaire). Since no major problems were detected with the study questionnaire or the instruction provided to the study participants, no significant modifications were made to the instrument, study design and method of recruitment of study participants.

5.2.2 Main Study

Data from the mall intercept survey were collected during June 2004 at two malls in the Atlanta metropolitan area through personal interviews. The sample consisted of 307 female respondents between the ages of 18-50 years. On average, each interview took approximately 15 minutes to complete. The time taken to observe the front page of the ad (ad copy) was noted. Further, we also observed whether the respondent had to be prompted to look at the back page (brief summary) and how long she examined the brief summary. On average, respondents looked at the front page of the ad for 65 seconds (SD=40 seconds). 37.6% respondents had to be prompted to look at and read the brief summary page (Figure 10) (where applicable, since 2 format versions did not have a brief summary). Furthermore, the average time taken by respondents to view the back page of the ad was 63 seconds (SD=68 seconds).

Sample Characteristics

Given that we desired 80% statistical power (1-beta), it was determined that we would need approximately 50 respondents assigned to each of the six brief summary formats (n=300). We distributed 310 questionnaires in order to account for missing data. We obtained 307 usable questionnaires (See Table 27).

The demographic composition of the sample is summarized in Table 16. The majority of respondents were Caucasian (60%), while approximately 27% were African-Americans. About 15% of the respondents had at least a four-year college degree. Most

women in the sample were below 35 years of age (86%), representing the main target population for the OrthoEvra DTC campaign.

Over 40% of the sample were currently taking a prescription drug for birth control and greater than 3/4ths of the respondents had used such a drug previously. Among the different types of birth control medications used by sampled subjects, 66% had used birth control pills at some point in the past, 10% of respondents had some experience using a patch (OrthoEvra®) and 6% had used a birth control ring. Magazine readership was believed to be a predictor for exposure and reaction to DTC ads, however, fewer than 10% of respondents reported reading consumer magazines more than 3 times a week, while over half of the sample reported reading magazines at least once a week. Greater than a third (36.8%) of the respondents reported reading Self™ magazine, which features the OrthoEvra ad.

Respondents' past exposure to DTC ads could be an important value driver of their reactions to such ads. Almost all respondents in our sample had seen a print DTC ad in the past. However, awareness and recall for prescription birth control medications was extremely low, with less than a fifth of the respondents (14%) reporting seeing such a DTC ad. Among current DTC birth control campaigns, OrthoTricyclen® (54%) OrthoEvra® (47%) and Yasmin® (31%) received high to moderately high aided recall ratings. The relatively high aided awareness of these ad campaigns must be interpreted with caution as high awareness ratings were reported (32%) for a false response check item (Contracept).

Validity of Random Assignment

Following Kerlinger (1968), a verification of the validity of the random assignment of the experimental manipulation was conducted to ensure group homogeneity. Chi-square tests were conducted to determine if the experimental cells differed with respect to demographics, past and current use of birth control and exposure to birth control ads. An alpha level of 0.05 was used for each of the chi-square tests. The experimental cells did not differ across the three demographic characteristics assessed in the study namely, age, race and education. In addition, no differences were detected between the cells with regard to respondents' utilization of birth control prescription drugs and past exposure to DTC ads for prescription birth control medications (See Table 29-34). Overall, the experimental groups were equivalent with respect to the demographic, utilization and ad exposure variables assessed in the study, thereby demonstrating that the random assignment of study subjects was indeed successful.

Post-hoc reliabilities of outcome measures

Prior to conducting univariate and multivariate analyses on the outcomes measured in the study, internal consistency reliabilities were computed for all measurement scales. In addition, these reliability measures were used as a correction for attenuation in the path analytic model described later in the chapter. All outcome measures demonstrated good internal consistency (0.87-0.94). Removing any items

from any of the scales did not substantially increase the internal consistency for that scale.

Descriptive statistics for outcome measures

Respondents' favorable perceptions towards the ad were evidenced by the high scores provided on rating scales (scored between 1-7) measuring quality of information in the ad. For example, the mean score for the evaluation of quality of risk information was 5.87 (SD=1.11) and mean score for quality of benefit information was 5.89 (SD=1.10). The evaluations of the quality of the brief summary were slightly lower than the risk and benefit information; having a mean score of 5.62 (SD=1.40). Consumers had positive opinions of ad believability with a mean score of 5.62 (SD=1.14). Similarly, attitude towards the ad, attitude towards the brand and intent to use ad information for health care decision-making received favorable ratings with mean scores of 5.75 (SD=1.20), 5.72 (SD=1.27) and 5.65 (SD=1.47) respectively. Consumers had slightly negative opinions of perceived product risk with a mean score of 3.36 (SD=1.55) (See Table 20).

On average consumers correctly identified 2.91 (SD=1.99) adverse drug reactions from the seven correct choices that were provided. They incorrectly identified 6.25 (SD=0.95) adverse drug reactions. Overall, respondents provided more incorrect answers to the adverse drug reaction scale and the mean score for the adverse drug reaction questionnaire was -3.34 (SD=2.15) (See table 22).

On average consumers correctly answered 3.19 (SD=1.37) of the six questions pertaining to drug risks and incorrectly answered 1.80 (SD=1.33) questions. On average, respondents answered 1.00 (SD=1.28) question as "don't know". Overall, the mean score for the knowledge of drug risks scale was 0.38 (SD=2.75) (See table 24).

Of the six questions that related to the benefits accruing from the use of OrthoEvra, respondents correctly answered 4.46 (SD=1.18) questions and incorrectly answered 1.66 (SD=0.94) questions. Overall, the mean score for the knowledge of drug benefits scale was 2.18 (SD=2.18) (See table 25).

An overall index for the knowledge of drug risks and benefits was computed using a summated score of each of the two aforementioned "knowledge of drug benefits" and "knowledge of drug risks" scales. Accordingly, the average number of correct answers to the overall knowledge measure was 7.66 (SD=2.09) (of a maximum of 12). On average, respondents provided 3.46 (SD=1.83) incorrect answers to the knowledge questions. Consumers answered, on average, 2.57 (SD=4.02) questions with a "don't know" response. Therefore, the overall score for the "knowledge of drug risks and benefits" was computed by subtracting the incorrect and "don't know" answers from the correct answers. This resulted in an overall mean score of 1.62 (SD=1.90) for the "knowledge of drug risks and benefits" scale (See table 26).

Difference in information processing between treatment groups

The experimental manipulation was hypothesized to influence 12 outcome variables measured in the study. The six different formats of the brief summary in the

ad were hypothesized to elicit different scores on eleven of the twelve outcome measures. The remaining outcome measure pertained to the evaluation of the quality of brief summary, which was measured only for four of the six formats (since two formats did not have a brief summary). The multivariate analysis-of-variance (MANOVA) test conducted on the eleven outcomes measured for all treatment groups revealed that there indeed existed significant differences across the six treatment groups (See table 35). Four different indicators of significance were used in the MANOVA test. Pillai's trace, Wilks' Lambda, Hotelling's Trace and Roy's Largest Root, tests of overall model significance based on the F distribution, were all significant ($p<0.000$).

Based on overall tests of multivariate significance, univariate analyses-of-variance (ANOVA) tests were conducted to determine which specific outcome variables (of the 11 outcomes measured in the study that concerned all formats) were influenced by the experimental manipulation. In addition, a single AVOVA was conducted for scores on evaluation of the quality of brief summary to determine significant differences within the 4 ad formats that did have a brief summary. If the manipulation was significant for a specific outcome variable, then post-hoc comparisons using the most conservative Scheffe's test were conducted to determine which specific formats differed significantly on that outcome measure.

The results of the univariate ANOVAs and the post-hoc Scheffe's test (where applicable) are discussed separately for each outcome variable below. Since 12 univariate ANOVAs were conducted to determine if there were differences on the outcome variables across treatment groups, a Bonferroni adjustment was applied to

reduce the family-wise error rate for the study. Accordingly, the α level at which the significance of the tests were interpreted was reduced from α=0.05 to α=0.004 (0.05/12).

1) Evaluation of quality of risk information

The p-value for the univariate ANOVA evaluating differences in the treatment groups with respect to evaluation of quality of risk information was 0.016, which is non-significant when a conservative alpha level of 0.004 is used for the test. Thus, the null hypothesis of no significant differences failed to be rejected. A visual comparison of the means revealed that evaluations of quality of risk information for the newer versions of the brief summary, specifically for the bulleted list, risk information window and nutrition facts panel were higher than those for the original brief summary, although they were not different enough to achieve statistical significance (See table 36).

2) Evaluation of quality of benefit information

The p-value for the univariate ANOVA evaluating differences in the treatment groups with respect to evaluation of quality of benefit information was 0.172, which is non-significant at an alpha level of 0.004. Thus, the null hypothesis of no significant differences failed to be rejected for this outcome measure (See table 36).

3) Knowledge of adverse drug reactions

The p-value for the univariate ANOVA evaluating differences in the treatment groups with respect to knowledge of adverse drug reactions was 0.000, which is significant compared to the alpha level of 0.004 used for the test. Thus, the null hypothesis of no significant differences was rejected.

Post-hoc comparisons were conducted using Scheffe's test. Only two of the newer formats, i.e the question-answer format and the nutrition facts panel format performed better than the format with no brief summary. There were no significant differences between the format with no brief summary and the format with the original brief summary. Despite the fact that the original brief summary did perform worse than the newer brief summary formats, these differences were not significant. There were no significant differences among the newer brief summary formats. The question-answer format performed the best on recall of adverse drug reactions caused by the drug (See table 39).

4) Knowledge of drug risks

A visual comparison of the means however showed that the original brief summary performed better than the format with no brief summary. The newer brief summary formats also performed better than the format with not brief summary, with the difference being as large as 1.3 questions; however the difference was not statistically significant. The newer brief summary formats also performed better than the original brief summary format, although these differences were not stark enough to

achieve statistical significance. The p-value for the univariate ANOVA evaluating differences in the treatment groups with respect to knowledge of risk information was 0.014, which is non-significant when a conservative alpha level of 0.004 is used for the test. Thus, the null hypothesis of no significant differences failed to be rejected (See table 40).

5) Knowledge of drug benefits

The p-value for the univariate ANOVA evaluating differences in the treatment groups with respect to knowledge of drug benefits was 0.614, which is non-significant at an alpha level of 0.004. Thus, the null hypothesis of no significant differences failed to be rejected for this outcome measure (See table 41).

6) Overall knowledge of the drug

The knowledge of drug risks and benefits was combined into a single measure "knowledge of drug risks and benefits". Again, the newer brief summary formats performed better than the format with no brief summary and the format with the original brief summary, with the difference being as large as 1.3 questions; however these differences were not large enough to achieve statistical significance. The p-value for the univariate ANOVA evaluating differences in the treatment groups with respect to overall knowledge of drug was 0.407, which is non-significant at the alpha level of 0.004 used for the test. Thus, the null hypothesis of no significant differences failed to be rejected for this outcome measure (See table 42).

7) Ad believability

The p-value for the univariate ANOVA evaluating differences in the treatment groups with respect to evaluation of ad believability was 0.373, which is non-significant at an alpha level of 0.004. Thus, the null hypothesis of no significant differences failed to be rejected for ad believability (See table 37).

8) Perceived product risk

The p-value for the univariate ANOVA evaluating differences in the treatment groups with respect to perceived product risk was 0.719, which is non-significant at an alpha level of 0.004. Thus, the null hypothesis of no significant differences failed to be rejected for perceived product risk, indicating that modifications to the way risk information about a prescription drug is presented to consumers does not make them feel differently about the risk entailed by using that product (See table 38).

9) Attitude towards the ad

The p-value for univariate ANOVA evaluating differences in the treatment groups with respect to attitudes towards the ad was 0.406, which is non-significant at an alpha level of 0.004. Thus, the null hypothesis of no significant differences failed to be rejected for this outcome measure, suggesting that presentation of risk information in a DTC ad make no difference to how consumers perceive the ad itself (See table 37).

10) Attitude towards the brand

The p-value for univariate ANOVA evaluating differences in the treatment groups with respect to the evaluation of quality of benefit information was 0.895, which is non-significant at an alpha level of 0.004. Thus, the null hypothesis of no significant differences failed to be rejected in this case, implying that perceptions toward the product do not change according to the manner and amount of risk information that is presented about the product (See table 37).

11) Use of ad information in decision-making

The p-value for univariate ANOVA evaluating differences in the treatment groups with respect to the evaluation of quality of benefit information was 0.685, which is non-significant at an alpha level of 0.004. Thus, the null hypothesis of no significant differences failed to be rejected for this outcome measure (See table 37).

12) Evaluation of quality of the brief summary

The p-value for the univariate ANOVA evaluating differences in the treatment groups with respect to evaluation of the brief summary specifically, was 0.000, which is significant compared to the alpha level of 0.004 used for the test. Thus, the null hypothesis of no significant differences was rejected here.

As the overall ANOVA revealed significant differences among the treatment group means, post-hoc comparisons were conducted using the Scheffe's test. The results revealed that the original brief summary performed poorer than the newer brief

summary formats. However, there were no significant differences among the newer brief summary formats. Interestingly, a visual comparison of the means shows that evaluations of quality of risk information were highest for the nutrition facts panel, followed by the bulleted list format and the question answer format. Nevertheless, the differences between the newer formats did not reach statistical significance (See table 43).

Differences between formats on attention to the ad

Univariate ANOVAs revealed no significant differences in attention measures (attention to the ad and the brief summary) across formats (table 44). A chi-square test was conducted to determine if the percentage of consumers reading the back page without prompting differed across formats. The chi-square test revealed no significant differences (table 44).

Differences between prompted and unprompted consumers

Univariate ANOVAs were conducted using a Bonferroni correction to test if the consumers who were prompted to read the brief summary differed from consumers who read the brief summary without prompting on any of the outcome measures. The ANOVAs revealed no significant differences at the corrected alpha=0.006 level (table 45). The two segments of consumers - consumers who were prompted to read the brief summary and those who read the brief summary without prompting – did not differ on any of the demographic characteristics or other covariates measured in this study.

Differences between knowledge of drug risks and benefits

A paired t-test was conducted to compare the knowledge scores for questions pertaining to drug risks and drug benefits. This test was performed in order to compare the extent of comprehension of drug risks vs. drug benefits. Data from all treatment groups were pooled together to conduct an overall test of significance across formats. The paired t-test revealed significant differences between the two knowledge scores (See table 46). A visual comparison of means showed that respondents comprehended the benefits of the drug more than risks across all formats.

To determine the specific formats in which consumers comprehended drug benefits better than drug risks, paired t-tests were conducted separately for each format. All paired t-tests were significant at $p<0.001$ (See table 46). Even after performing a Bonferroni adjustment (alpha=0.05/6 i.e. 0.008), all tests still revealed significant differences. Although the differences between the means are greater for the treatment groups with no brief summary and the original brief summary as compared to the groups with newer brief summary formats, even consumers exposed to the newer brief summary formats were able to correctly answer more questions related to drug benefits as compared to questions regarding drug risks.

Differences in evaluation of quality of drug risk and benefit information

To determine if consumers evaluated the quality of risk and benefit information differently across formats, a paired t-test was conducted to compare the evaluation of quality scores for risk and benefit information. This test examined whether DTC ads

communicated benefit information better than they did, risk information. Data from all treatment groups were pooled together to conduct an overall test of significance across formats. The paired t-test revealed that there was no significant difference between the qualities of the two types of information (See table 47). Since the overall test of significance with pooled data from all treatment groups did not achieve statistical significance, individual paired t-tests were not performed separately for each format.

Effect of risk information on attitude towards the brand

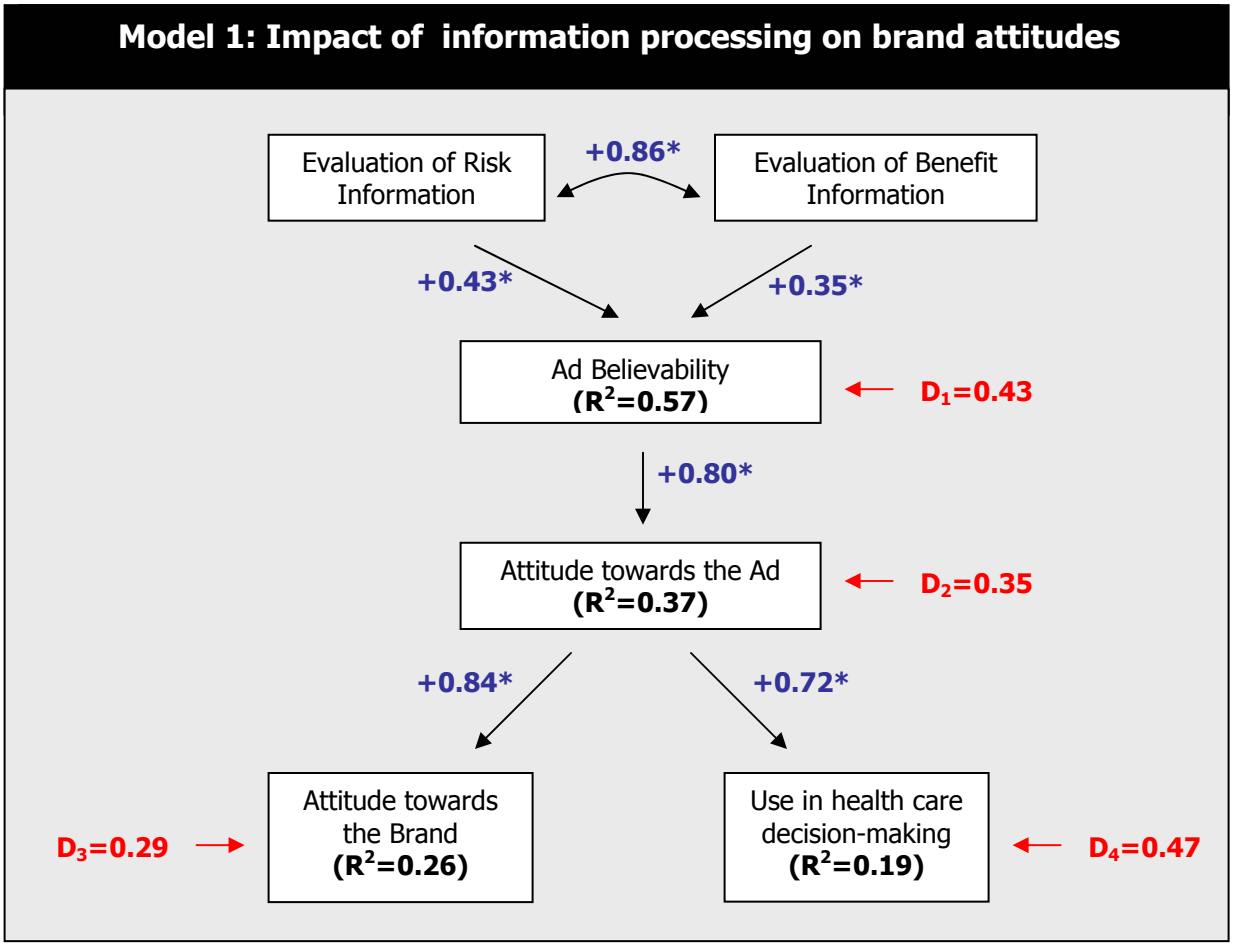
The two path analytical models proposed a priori were run using Lisrel v8.53. Model comparisons were conducted using several goodness-of-fit indices like chi-square, Normed Fit Index (NFI), Non Normed Fit Index (NNFI), Comparative Fit Index (CFI), Goodness of Fit Index (GFI) and Parsimony Goodness of Fit Index (PGFI). Significance testing of path coefficients from both models were conducted at alpha=0.05.

Model 1

This model proposed that evaluation of quality of risk information would positively influence brand attitudes through the mediating effect of ad believability and attitude toward the ad. All paths proposed in this model achieved statistical significance at the $p<0.01$ level. The path coefficients in the model were all in the hypothesized direction. Positive evaluations of the quality of risk information increased ad believability

and engendered positive attitudes towards the ad. Positive attitudes towards the ad in turn led to positive attitudes towards the brand.

This structural model had a significant chi-square test with 9 degrees of freedom ($p<0.01$) indicating that the proposed model does not fit the data well. However, since the chi-square goodness of fit test is sample size-dependent, other fit indices were examined to determine the fit of the model to the data. Accordingly, other goodness-of-fit indices for this model were very high, NFI =0.97, NNFI=0.96, GFI=0.94 and AGFI=0.87, indicating that the model fit the data extremely well (See table 49). R-square statistics in the model for the four dependent measures ranged from 0.19 to 0.57 (See table 50).



* Indicates paths are significant at p<0.01

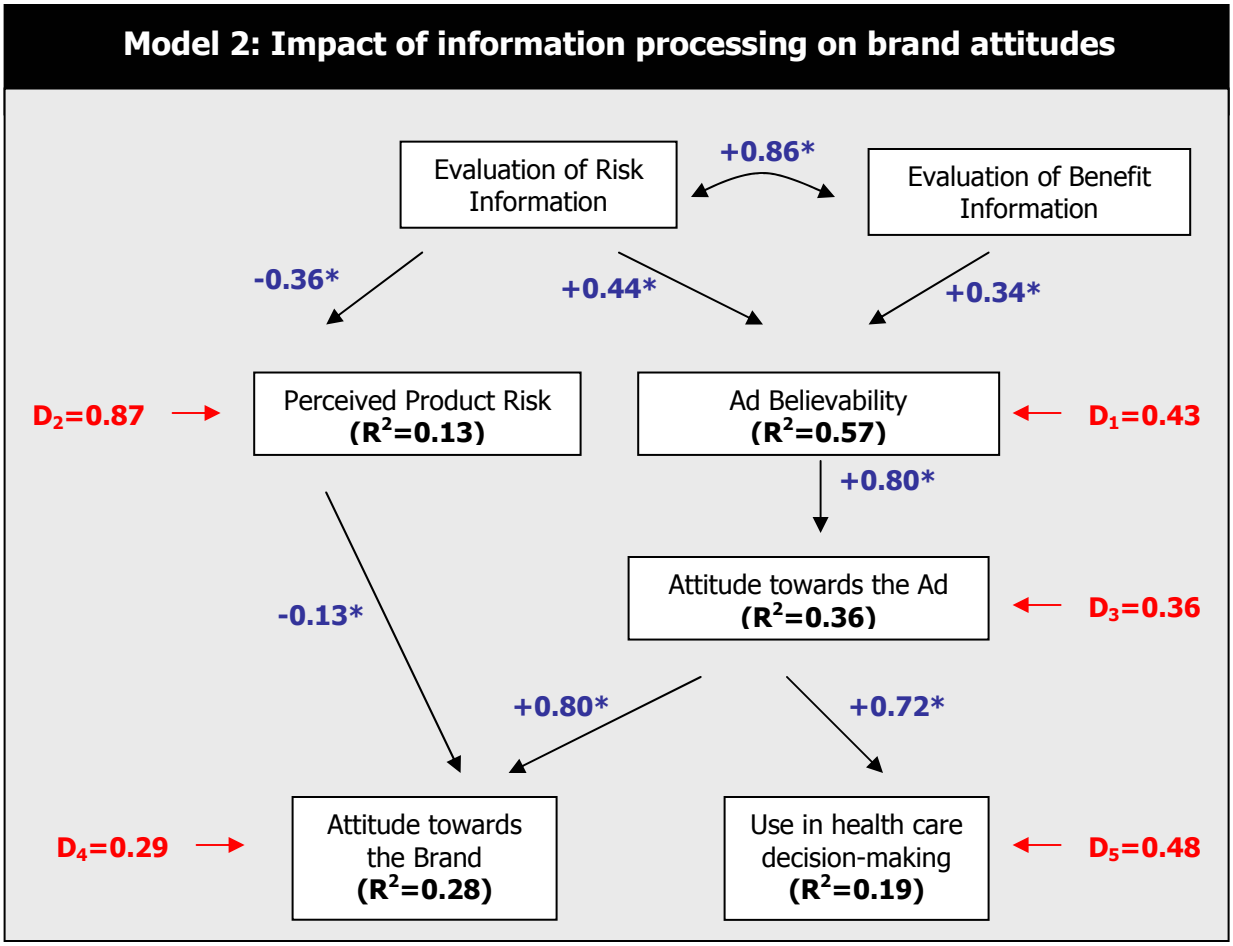
Figure 5: Path Coefficients for Proposed Study Model 1

Model 2

This model proposed that quality of risk information would negatively affect brand attitudes through the mediating effect of perceived product risk. Evaluation of quality of risk information was hypothesized to exert a positive effect on brand attitudes through the mediating effect of ad believability and attitude toward the ad. All paths proposed in this model achieved statistical significance at the p<0.01 level. However, not every path coefficient in the model was in the hypothesized direction. Positive

evaluations of the quality of risk information did not translate into a higher perceived product risk; rather it decreased the perceived riskiness of the product. This decreased perceived risk in turn, led to positive attitudes towards the brand. In addition, favorable evaluations of the quality of risk information increased ad believability and engendered positive attitudes towards the ad. Positive attitudes towards the ad in turn led to positive attitudes towards the brand. Thus, through both pathways i.e. the perceived risk pathway and the ad believability pathway, positive evaluations of the risk information were associated with positive brand attitudes.

This structural model had a significant chi-square test with 13 degrees of freedom ($p<0.01$) indicating that the proposed model does not fit the data well. However, other goodness-of-fit indices for this model were very high, NFI =0.96, NNFI=0.94, GFI=0.93 and AGFI=0.84, indicating that the model fit the data well (See table 49). R-square statistics in the model for the four dependent measures ranged from 0.13 to 0.57 (See table 51).



* Indicates paths are significant at p<0.01

Figure 6: Path Coefficients for Proposed Study Model 2

Model 1 vs. Model 2

Both models tested above showed that positive evaluations of the risk information were associated with positive brand attitudes. Although the chi-square test of model fit was significant in both models, the other sample size-independent goodness of fit statistics in both models met the criteria of acceptable model fit. Therefore, we can conclude that both models fit the data well. However, a comparison of the fit indices revealed that Model 1 performed better on all goodness-of-fit indices

than Model 2. An examination of the parsimony fit indices, Parsimony Normed Fit Index and PGFI, reveals that Model 1 performs better than Model 2 in providing an acceptable fit to the data while using fewer degrees of freedom. Inclusion of an additional variable in Model 2 helped gain only a slight increase in variance explained than Model 2 (26% vs. 28%). Since, Model 1 performed better than Model 2 and was more parsimonious, it was retained as the final model for explaining the effect of risk information on attitudes towards the brand.

CHAPTER 6

DISCUSSION AND IMPLICATIONS

6.1 Discussion of Study Results

The primary thrust of this study was to assess how different formats of the brief summary influence aspects of consumers' processing of risk and benefit information from DTC advertisements. Consequently, we tried to gain a better understanding of consumer preferences for information in drug ads and accordingly developed several formats of such information. These formats included the existing continuous prose brief summary, question-answer format, bulleted list format, the nutrition facts panel and the FDA-proposed risk information window format. Additionally, we also incorporated a control condition in our study (no brief summary) to test if presence of such information was at all required.

This study incorporated qualitative focus groups that helped gain insights into how consumers processed DTC ad information. Existing problems with the current brief summary were identified and consumers' preferences and evaluations of the newer brief summary formats were studied. In addition, the quantitative survey involved assessing consumers' responses on outcome measures such as a) Knowledge of the drug's adverse effects, risks and benefits; b) Affective attitudinal measures such as attitude towards the ad and brand; c) Cognitive evaluations such as ad believability,

quality of risk and benefit information and brief summary quality; d) Behavioral intention measures such a likelihood of using ad information in making health care decisions; and e) Perceived product risk.

The following chapter summarizes the conclusions drawn from both qualitative and quantitative insights. Specifically, we discuss the differential effects of the existing brief summary and its different manipulations on the aforementioned outcomes and the relationships between these outcome measures.

Necessity of a brief summary in print DTC ads

The findings of the focus group interviews imply that consumers desire that prescription drug ads carry some form of risk disclosure. In this context, the control condition (no brief summary) was rated poorly and perceived to be "incomplete". These results find support in the quantitative component of the study, which revealed that the presence of a brief summary positively influenced certain aspects of consumer information processing from DTC ads. For example, consumers recalled more information about adverse drug reactions when exposed to formats containing a brief summary versus no brief summary. A similar trend was observed in consumers' knowledge regarding drug risks, although this relationship failed to achieve significance, under conservative statistical procedures (Bonferroni adjustment).

Another interesting finding was that consumers' perceptions of product risk did not increase significantly when they were exposed to formats of the brief summary. We may infer from this finding that the mere presence of a risk disclosure, regardless of

format, does not seem to make consumers apprehensive about the safety of the product. This suggests that consumers are not "turned off" by seeing risk information in DTC ads. Several industry analysts have suggested in the past that DTC print ads should not be forced to carry a brief summary as it does not add value to the ad, but rather confuses consumers. Our study results demonstrate that consumers desire risk information in DTC ads and the brief summary positively influences consumers' knowledge of drug risks. In addition, presence of a brief summary does not make the product seem less safe to consumers. This may allay fears of those marketing practitioners who perceive that providing detailed and specific product risk and side effect information does not make consumers apprehensive of using the product.

Alternatively, it is possible that consumers are so conditioned to seeing risk and warning information by their exposure to numerous ad stimuli on a daily basis, that their perception of the product's safety is not affected by the presence of a risk disclosure. Considering that consumers desire a brief summary in print DTC ads, and that perceived product risk is not influenced by presence of such information, the results of this study provide some support for the continual provision of a brief summary in print DTC ads.

Newer and recently proposed formats of the brief summary

The FDA recently issued a draft guidance urging pharmaceutical manufacturers to implement more consumer-friendly brief summaries (FDA 2003). Examples included the question-answer format and the risk information window. A recent poll of drug

marketers conducted by the FDA showed that over a third of practitioners intended to use such newer brief summary formats (DTC Perspectives 2004). Nevertheless, evidence of the impact of these formats on consumer information processing remains inconclusive. The findings reported here provide some insights that form the groundwork for addressing this issue.

The discussions during the focus group interviews revealed that participants were dissatisfied with the manner of the presentation of the existing brief summary. The major drawbacks to information processing from the brief summary as identified by focus group participants included small font size, overwhelming amount of information and the technicality of the information. Focus group participants reported being unable to comprehend and interpret medical terms used in the brief summary (e.g. "myocardial infarctions" and "hepatic neoplasia"). The amount of information overwhelmed the participants to the point where they did not want to read the information any more. The font size used in the brief summary was deemed "unreadable" and seemed to discourage information acquisition. Based on the responses elicited during focus groups, we suggest the need for newer formats of the brief summary that facilitate readability and comprehension of information.

Most focus group participants reported they would rather spend time on the Internet browsing for more information rather than read the fine print in the brief summary. While there are websites that are approved for their quality by organizations such as the HON foundation, several websites on the Internet have information that has not been approved by the FDA. Considering that DTC ads spur information search on

the Internet, perhaps, consumers may be misled by inaccurate information from disingenuous websites. While the brief summary does need to educate consumers about the prescription drug, it also needs to be designed to be clearer and more understandable. The amount of information contained in the current brief summary devalues its inherent purpose – to assist consumers in deciding whether the drug is appropriate.

Based on the insights gained from the qualitative study, we developed newer formats that incorporated the views of the focus group participants and adhered to the FDA's guidance and recommendations on brief summary presentation. These formats were later tested using a monadic experimental design. In the qualitative study, participants were much more favorable to the newer brief summary formats, specifically to the question-answer format. The question-answer format was preferred because of the similarity of information presentation to the typical doctor-patient consultation. Participants reported that they would definitely spend time reading the brief summary if it were communicated in one of the four newer formats (Q/A, bullet-list, nutrition facts panel, risk information window).

In the quantitative study, respondents assigned to the treatment groups that received newer brief summary rated these brief summaries much higher than the group receiving the original brief summary. These formats were rated particularly highly on their readability and clarity.

Based on the findings of the quantitative study, newer formats of the brief summary do not seem to increase consumer apprehension about the risk of using the

product. This was evidenced by the lack of significant differences found across formats in perceived product risk. Unambiguous trends were also visible in the superiority of newer formats on consumers' knowledge of specific drug information such as adverse effects. Specifically, respondents in the mall intercept study recalled more adverse events associated with the drug when exposed to ads containing newer brief summaries.

Newer formats performed similarly better on other outcome measures such as knowledge of drug risks. On average, study respondents scored -0.15 on knowledge of drug risks, while for newer brief summary formats the mean knowledge scores were positive and ranged from 0.58 to 0.98, although these differences failed to achieve significance under conservative statistical testing. On average, overall knowledge about the drug (a summated index of drug risk and drug benefit knowledge scores) was 2.62 for the existing brief summary, but ranged from 3.17 to 3.92 for the other formats. Although, this difference failed to achieve statistical significance, the results of the quantitative study provide some evidence that consumers exposed to the newer formats may have more knowledge about the advertised drug as compared to group receiving the existing format. This suggests that consumers may benefit from the use of any one of the newer brief summary formats. But does one of these newer formats perform comparatively better on an outcome?

The qualitative results clearly demonstrated that focus group participants preferred the brief summary information when it is conveyed in the form of question and answers. However, any particular single format from among the newer formats did

not seem to perform better that the others on quantitative outcomes. Although the newer formats performed better than the existing format and the format with no brief summary on outcomes such as evaluation of the brief summary and knowledge of the advertised drug, there were no apparent differences between these newer formats themselves. Perhaps, there is no clear superior among the newer formats. It seems clear however, that the time to do away with the existing format has arrived.

A comparison of mean scores on knowledge of drug risks and benefits across all formats revealed that respondents' recollection of drug benefits was greater than their recollection of drug risks. Possibly, using the newer formats may not ensure an equitable learning of drug risk and benefit information. The findings imply that consumers may want to know more about what the drug may be able to do for them rather than about the possible hazards associated with its use.

Relationship between risk communication and attitude towards the brand

We proposed to evaluate two theoretical models that tested competing hypotheses concerning the effect of risk information on brand attitudes. It has been argued that presenting information about negative product attributes within a promotional message improves the credibility of the message. This was the effect we hypothesized in the first model. The results of the model testing exercise indicate that the hypothesized effect may hold true in pharmaceutical advertising. The acceptable fit of the first model along with the significance and directionality of the path coefficients demonstrate that favorable perceptions of the quality of the risk information may

improve ad believability. In turn, this could engender favorable attitudes towards the ad and brand and, may increase the likelihood of using ad information in decision-making.

Drawing from previous research in the alcohol and tobacco warning literature, we tested the second model that hypothesized that clearer risk information would increase perceived product risk, which would in turn lead to negative attitudes towards the advertised brand. The results reveal that these relationships were indeed significant, although, in a direction contrary to that hypothesized. In fact, this model suggests that favorable perceptions of the quality of risk information may not increase perceived product risk, but rather make the product appear less risky. This may be due to the fact that when the risk information is not understandable and clear, consumers may be overwhelmed with the information. This may lead to them believing that the product is riskier. However, when they understand the risk information in the ad, they may feel more comfortable about the product risks, leading to a decreased perceived product risk. Favorable perceptions of product risk may lead to positive attitudes towards the advertised brand. Overall, it seems that through either of the competing pathways that were evaluated in this study, risk information positively influences brand attitudes.

The results of this research have significant public policy and marketing ramifications. As such, diverse audiences may be able to make prudent use of these findings. Based on the findings reported here, it appears that provision of risk information in a clear and understandable format may not negatively influence brand attitudes. While the literature in both academic and trade circles reveals an

apprehension on the part of the industry to provide consumers information about drug risks lest they create a fear of taking prescription drugs, the findings reported here should allay such worries. The findings of this research encourage the incorporation of clear and comprehensible risk communication when marketing prescription drugs. Positive perceptions of the quality of risk and benefit information in the advertisement also make the ad more believable. In this context, an examination of the path coefficients in model 1 indicates that the quality of risk information is perceived to be a more important feature of DTCA than the quality of benefit information in its sheer impact on message believability. This may lend support to the notion that provision of information about the negative attributes of a product does indeed improve the credibility of the message. While risk and benefit information in a drug ad need to be balanced, manufacturers would be loath to undervalue or underestimate the importance of risk information.

6.2 Conclusions and Implications

The primary goal of this research was to develop a better understanding of how drug risks may be more effectively communicated to consumers and patients through the brief summary in print DTC ads. The findings reported from the experimental component of this study are unique in empirically revealing the nature and extent of consumers' information processing from existing and newer brief summaries. In addition, the qualitative component of this study provides substantial information about

consumers' informational preferences in a brief summary for a personally relevant drug product.

Overall, this research attempts to deliver to its audience, current and relevant insights into consumers' information processing from the brief summary in DTC ads. The results of this study are congenial to the interests of multiple audiences such as regulators, consumer advocates, marketers and academic researchers. We hope that the findings reported here will influence regulatory policies, drug marketing practices and patient medication behaviors in the near future, as DTC expenditure and drug utilization witness continued growth.

Knowledge about consumer preferences and desires that suggest a need for change to the existing brief summary format may help in the development of a standardized regulatory structure for risk communication in DTC ads. The several complaints that focus group participants reported with the existing brief summary uncovered by our research will allow the FDA to develop newer standards for the future. The implications of this study may provide regulators additional insights about risk communication in DTC ads, considering that the FDA is expected to announce new guidelines regarding the brief summary in DTC ads in the near future.

In addition to catering to the regulatory and public policy audience, this research also has ramifications for the marketing of prescription medications. We hope that the results reported here will assist pharmaceutical marketers in gaining a better understanding of how to incorporate effective risk communication within their promotional plan. In the past, it has been theorized that marketers fear the

incorporation of clear and comprehensive risk communication, as it would scare consumers away from using the prescription drug. However, our results show that the presence of a brief summary does not negatively influence perceived product risk. Perhaps, the information over-load that focus group participants reported in the existing brief summary could be averted by using one of the newer formats. In addition, the findings suggest that incorporating risk information that is more comprehensible, may elicit more favorable perceptions towards the ad and brand and may possibly stimulate product trial and adoption.

6.3 Limitations and Future Research

The findings of this study must be cautiously interpreted in light of its limitations. Although this study is unique in investigating the influence of newer brief summary formats on consumers' information processing, the following caveats remain:

1) The ecological validity of the study findings must be interpreted in light of the fact that respondents in the mall intercept study were administered only a single forced exposure to the ad stimulus. Furthermore, a cross-sectional study design such as that employed here may offer only transitory information about consumers' processing of information from the brief summary. Consumers' knowledge about the advertised drug, resulting attitudes toward the ad and brand, and behavioral intentions are liable to evolve with the passage of time. In this regard, longitudinal studies may provide a more

complete understanding of the trends and patterns in consumers' information processing from the brief summary.

2) The findings reported here are subject to the limitations that plague all experimental research. The study results have limited generalizability because of limited representativeness that is endemic to any convenience sample. This study utilized a single ad and studied a single therapeutic class using a target population of only women. Moreover, the environment within which the mall intercept personal interviews were conducted is considered to be sterile and plagued by artificiality. In other words, the conditions under which respondents were exposed to the ad and answered the questions were isolated and different from the typical advertising exposure environment. Such ad testing conditions may introduce additional bias into the study findings.

3) Respondents to the mall intercept survey were asked to read the ad and answer questions to an approximately 15 minute-long questionnaire. This act itself required a certain degree of educational capability and literacy level that may not be representative of the general consumer population that is exposed to DTC ads.

4) This study also used an existing ad for a birth control patch that was being advertised during the study period both on TV and in *Self*™ magazine. Since respondents to the mall intercept survey may have been exposed to this ad in the past,

existing attitudes towards the ad and/or product may have influenced how information was processed in the ad stimuli. We did however try to control this spurious effect through random assignment. As post-hoc analyses revealed, the six treatment groups did not differ with respect to any demographic characteristics, health care utilization variables, and past exposure to DTC ads, we may be reasonably confident of the validity of the responses.

5) Common method variance may account for correlation between several of the outcome measures in the quantitative study, thereby leading to spurious relationships in the study model. Many of the outcome measures were assessed similarly, i.e. using 7-point semantic differential scales. Therefore, it is possible that respondents in the mall intercept study may have been conditioned to respond to the scales in a very similar manner, thereby leading to highly correlated measures. In future, researchers should attempt to use measures that are able to better discriminate between responses to these outcome variables.

6) Although we argue that processing of risk information may ultimately influence consumer behavior, in this particular study, there is no attempt to measure actual behavior as an outcome of risk information processing from DTC ads.

In light of the limitations of the current study, a promising area for future investigation is to examine the factors influencing consumers' attention to and information processing from the brief summary in more natural settings. Moreover, a

validation of the study results in a national sample, across therapeutic areas, is warranted to establish the validity of the conclusions reported here. Attention to the brief summary could be measured using eye-tracking techniques. Finally, an interesting line of inquiry is to assess health care professionals' attitudes towards the newer brief summary formats and their perception of the adequacy of the information contained therein.

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TABLES

Table 8. Scale Reliability: Evaluation of the quality of risk information

N = 305
Number of items = 7
Cronbach's Alpha = 0.908

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
q3a Evaluation of risk information – READABLE	35.164	44.545	0.705	0.896
q3b Evaluation of risk information – CLEAR	35.220	43.271	0.792	0.886
q3c Evaluation of risk information – COMPLETE	35.298	45.092	0.717	0.895
q3d Evaluation of risk information – ACCURATE	35.328	45.596	0.717	0.895
q3e Evaluation of risk information – INFORMATIVE	35.164	45.670	0.726	0.894
q3f Evaluation of risk information - UNDERSTANDABLE	35.190	44.280	0.748	0.891
q3g Evaluation of risk information – BELIEVABLE	35.325	44.970	0.666	0.901

Table 9. Scale Reliability: Evaluation of the quality of benefit information

N = 306
Number of items = 7
Cronbach's Alpha = 0.925

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
q4a Evaluation of benefit information – READABLE	35.176	44.834	0.719	0.918
q4b Evaluation of benefit information – CLEAR	35.307	43.656	0.787	0.911
q4c Evaluation of benefit information – COMPLETE	35.333	44.334	0.777	0.912
q4d Evaluation of benefit information – ACCURATE	35.425	44.232	0.794	0.911
q4e Evaluation of benefit information – INFORMATIVE	35.271	44.080	0.773	0.912
q4f Evaluation of benefit information - UNDERSTANDABLE	35.255	44.295	0.770	0.913
q4g Evaluation of benefit information – BELIEVABLE	35.428	44.318	0.726	0.917

Table 10. Scale Reliability: Evaluation of the quality of brief summary

N = 202
Number of items = 7
Cronbach's Alpha = 0.949

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
q5a Evaluation of brief summary information - READABLE	33.688	68.166	0.810	0.943
q5b Evaluation of brief summary information – CLEAR	33.817	69.474	0.836	0.940
q5c Evaluation of brief summary information - COMPLETE	33.584	71.956	0.827	0.940
q5d Evaluation of brief summary information - ACCURATE	33.782	72.251	0.835	0.940
q5e Evaluation of brief summary information - INFORMATIVE	33.708	70.735	0.840	0.939
q5f Evaluation of brief summary information - UNDERSTANDABLE	33.703	69.991	0.838	0.939
q5g Evaluation of brief summary information - BELIEVABLE	33.678	72.189	0.809	0.942

Table 11. Scale Reliability: Ad believability

N = 303
Number of items = 10
Cronbach's Alpha = 0.943

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
q6a Ad Believability - Believable	50.251	105.096	0.802	0.936
q6b Ad Believability - Trustworthy	50.584	105.621	0.814	0.935
q6c Ad Believability - Convincing	50.515	105.926	0.801	0.936
q6d Ad Believability - Credible	50.620	106.435	0.800	0.936
q6e Ad Believability - Reasonable	50.406	107.699	0.766	0.937
q6f Ad Believability – Honest	50.525	105.568	0.795	0.936
q6g Ad Believability - Unquestionable	50.941	104.546	0.722	0.940
q6h Ad Believability - Conclusive	50.739	104.895	0.797	0.936
q6i Ad Believability - Authentic	50.492	110.529	0.614	0.944
q6j Ad Believability – Likely	50.531	105.925	0.760	0.938

Table 12. Scale Reliability: Attitudes towards the ad

N = 306
Number of items = 3
Cronbach's Alpha = 0.870

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
q7a Attitudes towards ad - Good	11.343	6.508	0.716	0.847
q7b Attitudes towards ad - Pleasant	11.529	5.883	0.820	0.751
q7c Attitudes towards ad - Favorable	11.598	6.064	0.720	0.846

Table 13. Scale Reliability: Attitudes towards the brand

N = 305
Number of items = 3
Cronbach's Alpha = 0.898

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
q8a Attitudes towards brand - Good	11.321	6.982	0.812	0.845
q8b Attitudes towards brand - Positive	11.459	6.986	0.802	0.853
q8c Attitudes towards brand - Favorable	11.521	6.356	0.789	0.867

Table 14. Scale Reliability: Likelihood of using ad information in decision-making

N = 306
Number of items = 3
Cronbach's Alpha = 0.934

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
q9a Use of ad information - Likely	11.232	8.349	0.871	0.900
q9b Use of ad information - Probable	11.350	9.284	0.880	0.893
q9c Use of ad information - Possible	11.327	9.047	0.845	0.918

Table 15. Scale Reliability: Perceived product risk

N = 305
Number of items = 5
Cronbach's Alpha = 0.915

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
q10a Risk perception - Dangerous	13.452	39.854	0.794	0.893
q10b Risk perception – afraid	13.570	38.851	0.781	0.895
q10c Risk perception – side effects likely	13.311	38.570	0.769	0.898
q10d Risk perception - greater risks vs. benefits	13.357	39.842	0.779	0.896
q10e Risk perception – very risky	13.495	39.363	0.787	0.894

Table 16. Sample descriptives - Demographics

Variable	Levels	Frequency (n)	Percent (%)
Age	1 18-20	129	42.02%
	2 21-25	67	21.82%
	3 26-30	44	14.33%
	4 31-35	26	8.47%
	5 36-45	23	7.49%
	6 46-50	18	5.86%
Race	1 American Indian	2	0.65%
	2 Asian	17	5.54%
	3 African-American	83	27.04%
	4 Hispanic	10	3.26%
	5 Pacific Islander	2	0.65%
	6 Caucasian	185	60.26%
	7 Other	8	2.61%
Education	1 Less than high school	30	9.77%
	2 High school graduate	123	40.07%
	3 Associates degree	47	15.31%
	4 Some college	58	18.89%
	5 College graduate	40	13.03%
	6 Graduate school or higher	9	2.93%

Table 17. Sample descriptives - Past and current use of birth control drugs

Variable	Levels	Frequency (n)	Percent (%)
Current use of Birth Control drugs	Yes	131	42.80%
	No	175	57.20%
Past use of Birth Control drugs	Yes	237	77.20%
	No	70	22.80%
Past/Current use of specific Birth Control drugs	Patch*	33	10.70%
	Pill*	204	66.40%
	Ring*	20	6.50%

* Cells do not sum up to a 100% due to membership in multiple categories

Table 18. Sample descriptives – Magazine readership

Variable	Levels	Frequency (n)	Percent (%)
Frequency of magazine readership	Never	19	6.20%
	Once a month	113	36.90%
	Once a week	95	31.00%
	2-3 times a week	55	18.00%
	Greater than 3 times a week	24	7.80%
Readership of specific magazines*	Ladies Home Journal	56	18.20%
	Self	113	36.80%
	Cosmopolitan	179	58.50%
	Good housekeeping	81	26.40%
	Prevention	38	12.40%

* Cells do not sum up to a 100% due to membership in multiple categories

Table 19. Sample descriptives – Exposure to DTC ads

Variable	Levels	Frequency (n)	Percent (%)
Past exposure to print DTC ads	Yes	271	88.30%
	No	36	11.70%
Past exposure to DTC ad for Birth control Rx*	Yasmin®	98	31.90%
	OrthoTricyclen®	168	54.70%
	Contracept#	100	32.60%
	OrthoEvra®	145	47.20%
	Seasonale®	18	5.90%
Exposure to a real DTC ad for Birth control Rx+	Yes	43	14.00%
	No	264	86.00%

* Cells do not sum up to a 100% due to membership in multiple categories
# Contracept is a fictitious drug which was used as a check for false responses
+ Contracept was excluded from this calculation

Table 20. Sample descriptives – Outcome measures

Scales	n#	Min	Max	Median	Mean	SD
Evaluation of the quality of risk information in the ad	305	1	7	6.14	5.87	1.11
Evaluation of the quality of benefit information in the ad	306	1	7	6.14	5.89	1.10
Evaluation of quality of the brief summary in the ad*	202	1	7	6.14	5.62	1.40
Ad believability	303	1	7	5.90	5.62	1.14
Attitudes towards the ad	306	1	7	6.00	5.75	1.20
Attitudes towards the brand	305	1	7	6.00	5.72	1.27
Use of ad information in decision-making	306	1	7	6.00	5.65	1.47
Perceived product risk	305	1	7	3.20	3.36	1.55

* Only asked of respondents exposed to an ad that had a brief summary on the back page.
# n < 307 due to missing responses on some items

Table 21. Sample descriptives – Frequencies of adverse drug reactions

Adverse Drug Reaction	Correct Response (Yes)	Incorrect Response (No)
Breast symptoms	46.30%	53.70%
Headache	57.00%	43.00%
Application site reaction	20.20%	79.80%
Nausea	68.10%	31.90%
Menstrual cramps	43.60%	56.40%
Upper respiratory infection	18.60%	81.40%
Abdominal pain	37.50%	62.50%
Adverse Drug Reaction	**Correct Response (No)**	**Incorrect Response (Yes)**
Glaucoma	94.50%	5.50%
Ulcers	96.70%	3.30%
Dizziness	65.50%	34.50%
Hallucinations	99.00%	1.00%
Insomnia	95.10%	4.90%
Drowsiness	79.20%	20.80%
Diabetes	95.40%	4.60%

Table 22. Sample descriptives – Knowledge of adverse drug reactions

Scales	n	Min	Max	Mean	Median	SD
Adverse drug reactions correctly responded (# rights)	307	0	7	2.91	3.00	1.99
Adverse drug reactions incorrectly responded (#wrongs)	307	0	7	6.25	7.00	0.95
Total score for adverse drug reaction scale (# rights - # wrongs)	307	-7	7	-3.34	-4.00	2.15

Table 23. Sample descriptives – Frequencies on knowledge items

Knowledge items	Type of question	% correct	% incorrect	% don't know
Protects against HIV/AIDS & STDs	Drug benefits	96.10%	1.30%	2.60%
Safety and effectiveness comparison with oral contraceptives	Drug benefits	42.00%	37.50%	20.50%
% Effectiveness of OrthoEvra	Drug benefits	91.20%	6.20%	2.60%
How often OrthoEvra needs to be changed	Drug benefits	84.70%	12.40%	2.90%
Use with caution in water	Drug benefits	69.40%	20.20%	10.40%
Use in emergency contraception	Drug benefits	63.50%	13.70%	22.80%
Smoking increases risks of side effects	Drug Risks	77.90%	17.90%	4.20%
Increased risks of blood clots	Drug Risks	76.50%	12.70%	10.70%
Overdosage symptoms	Drug Risks	50.80%	24.10%	25.10%
OrthoEvra should be used with precaution in certain populations	Drug Risks	17.90%	59.30%	22.80%
Contraindicated in nursing women	Drug Risks	64.50%	11.70%	23.80%
Contraindicated when family history of cancer	Drug Risks	31.60%	54.40%	14.00%

Table 24. Sample descriptives – Knowledge of drug risks

Scales	n	Min	Max	Mean	Median	SD
Knowledge questions pertaining to drug risks correctly responded	307	0	6	3.19	3.00	1.37
Knowledge questions pertaining to drug risks incorrectly responded	307	0	5	1.80	2.00	1.33
Knowledge questions pertaining to drug risks responded don't know	307	0	6	1.00	1.00	1.28
Total score for knowledge questions pertaining to drug risks	307	-6	6	0.384	0.00	2.75

Table 25. Sample descriptives – Knowledge of drug benefits

Scales	n	Min	Max	Mean	Median	SD
Knowledge questions pertaining to drug benefits correctly responded	307	1	6	4.46	5.00	1.18
Knowledge questions pertaining to drug benefits incorrectly responded	307	0	5	1.66	2.00	0.94
Knowledge questions pertaining to drug benefits responded don't know	307	0	5	0.61	0.00	0.94
Total score for knowledge questions pertaining to drug benefits	307	-4	5	2.18	3.00	2.18

Table 26. Sample descriptives – Knowledge of drug risks and benefits

Scales	n	Min	Max	Mean	Median	SD
Knowledge questions correctly responded	307	1	12	7.66	8.00	2.09
Knowledge questions incorrectly responded	307	0	9	3.46	3.00	1.83
Knowledge questions responded don't know	307	-10	11	2.57	3.00	4.02
Total score for knowledge questions	307	0	11	1.62	1.00	1.90

Table 27. Sample descriptives – Study site

Mall	Frequency (n)	Percent (%)
1 Gwinnett Place Mall	151	49.20%
2 Mall of Georgia	156	50.80%

Table 28. Sample descriptives – Format of brief summary

Cell - Brief Summary Format	Frequency (n)	Percent (%)
1 No Brief summary	51	16.61%
2 Risk Information window	51	16.61%
3 Original Brief Summary	51	16.61%
4 Question-Answer format	51	16.61%
5 Bulleted List format	52	16.94%
6 Nutrition Facts panel format	51	16.61%

Table 29. Differences across formats - Age

Variable		No Brief summary	Risk Information window	Original Brief Summary	Question-Answer format	Bulleted List format	Nutrition Facts panel format	Total
Age	18-20 yrs	28	17	24	19	18	23	129
	21-25 yrs	9	11	14	8	13	12	67
	26-30 yrs	7	10	4	12	5	6	44
	Greater than 30 yrs	7	13	9	12	16	10	67
Total		51	51	51	51	52	51	307

Chi-square = 17.542
p-value = 0.287

Table 30. Differences across formats - Education

Variable		No Brief summary	Risk Information window	Original Brief Summary	Question-Answer format	Bulleted List format	Nutrition Facts panel format	Total
Educat-ion	Less than high school	7	4	6	7	2	4	30
	High school graduate	20	20	23	22	16	22	123
	Associates degree	6	8	4	11	13	5	47
	Some college	11	8	9	6	13	11	58
	College graduate or higher	7	11	9	5	8	9	49
Total		51	51	51	51	52	51	307

Chi-square = 19.256
p-value = 0.505

Table 31. Differences across formats - Race

Variable		No Brief summary	Risk Information window	Original Brief Summary	Question-Answer format	Bulleted List format	Nutrition Facts panel format	Total
Race	Caucasians	35	31	26	32	33	28	185
	African Americans	8	16	16	12	14	17	83
	Other minorities	8	4	9	7	5	6	39
Total		51	51	51	51	52	51	307

Chi-square = 8.581
p-value = 0.572

Table 32. Differences across formats – Past use of birth control drugs

Variable		No Brief summary	Risk Information window	Original Brief Summary	Question-Answer format	Bulleted List format	Nutrition panel format	Total
Past use of Birth Control prescription drugs	**No**	10	11	18	10	7	14	70
	Yes	41	40	33	41	45	37	237
Total		51	51	51	51	52	51	307

Chi-square = 38.360
p-value = 0.137

Table 33. Differences across formats – Current use of birth control drugs

Variable		No Brief summary	Risk Information window	Original Brief Summary	Question-Answer format	Bulleted List format	Nutrition panel format	Total
Current use of Birth control prescription drugs	**No**	21	25	18	21	25	21	131
	Yes	29	26	33	30	27	30	175
Total		50	51	51	51	52	51	306

Chi-square = 2.694
p-value = 0.747

Table 34. Differences across formats – Exposure to a DTC ad for birth control

Variable		No Brief summary	Risk Information window	Original Brief Summary	Question-Answer format	Bulleted List format	Nutrition panel format	Total
Exposure to a real DTC ad for Birth control Rx	**No**	6	5	8	9	5	10	43
	Yes	45	46	43	42	47	41	264
Total		51	51	51	51	52	51	307

Chi-square = 3.802
p-value = 0.578

Table 35. Differences across formats – MANOVA results for all outcome measures

Multivariate test	Value	F statistic	Hypothesis df	Error df	Significance
Pillai's Trace	0.274	1.682	50	1450	0.002
Wilks' Lambda	0.750	1.706	50	1308	0.002
Hotelling's Trace	0.303	1.726	50	1422	0.001
Roy's Largest Root	0.157	4.555	10	290	0.000

Table 36. Differences across formats – Evaluation of ad information

Outcome Measure	No brief summary	Original Brief summary	Risk Information Window	Question Answer Format	Bulleted List format	Nutrition Facts Panel	F	p-value
Evaluation of quality of risk information in the ad	5.98	5.43	6.00	5.70	6.10	6.03	2.83	0.016
Evaluation of quality of benefit information in the ad	6.03	5.62	6.04	5.68	6.04	5.91	1.55	0.172
Evaluation of quality of brief summary information in the ad	n/a	4.76 A	n/a	5.76 B	5.94 B	6.01 B	10.04	0.000

Note: Scheffe's post-hoc multiple comparisons were used to test differences across formats when the univariate ANOVA was significant at the $p<0.004$ level. An alpha level of 0.004 was used after applying a Bonferroni correction (0.05/12). Groups marked with the same letter do not significantly differ from each other.

Table 37. Differences across formats – Evaluation of ad

Outcome Measure	No brief summary	Original Brief summary	Risk Information Window	Question Answer Format	Bulleted List format	Nutrition Facts Panel	F	p-value
Ad believability	5.69	5.31	5.63	5.65	5.81	5.61	1.078	0.373
Attitudes towards the ad	5.86	5.48	5.63	5.81	5.96	5.73	1.019	0.406
Attitudes towards the brand	5.82	5.60	5.48	5.78	5.95	5.66	0.895	0.484
Use of ad information in decision-making	5.71	5.61	5.76	5.39	5.88	5.56	0.685	0.635

Note: Scheffe's post-hoc multiple comparisons were used to test differences across formats when the univariate ANOVA was significant at the $p<0.004$ level. An alpha level of 0.004 was used after applying a Bonferroni correction. Groups marked with the same letter do not significantly differ from each other.

Table 38. Differences across formats – Perceived product risk

Outcome Measure	No brief summary	Original Brief summary	Risk Information Window	Question Answer Format	Bulleted List format	Nutrition Facts Panel	F	p-value
Perceived product risk	3.41	3.25	3.11	3.37	3.40	3.61	0.579	0.719

Note: Scheffe's post-hoc multiple comparisons were used to test differences across formats when the univariate ANOVA was significant at the $p<0.004$ level. An alpha level of 0.004 was used after applying a Bonferroni correction. Groups marked with the same letter do not significantly differ from each other.

Table 39. Differences across formats – Adverse drug reaction questionnaire

Outcome Measure	No brief summary	Original Brief summary	Risk Information Window	Question Answer Format	Bulleted List format	Nutrition Facts Panel	F	p-value
# of adverse drug reactions correctly responded	1.90	2.59	2.92	3.67	2.94	3.45		
# of adverse drug reactions incorrectly responded	6.24	6.33	6.41	6.16	6.15	6.24		
Score for adverse drug reaction scale (RIGHTS-WRONGS)	-4.33 A	-3.75 A B	-3.49 A B	-2.49 B	-3.21 A B	-2.78 B	5.263	0.000

Note: Scheffe's post-hoc multiple comparisons were used to test differences across formats when the univariate ANOVA was significant at the $p<0.004$ level. An alpha level of 0.004 was used after applying a Bonferroni correction. Groups marked with the same letter do not significantly differ from each other.

Table 40. Differences across formats – Knowledge pertaining to drug risks

Outcome Measure	No brief summary	Original Brief summary	Risk Information Window	Question Answer Format	Bulleted List format	Nutrition Facts Panel	F	p-value
# of knowledge items on risks correctly responded	2.66	2.92	3.29	3.41	3.36	3.49		
# of knowledge items on risks incorrectly responded	2.17	1.7	1.92	1.58	1.75	1.66		
# of knowledge items on risks responded with a don't know	1.15	1.37	0.78	1.00	0.88	0.84		
Score for drug risk knowledge scale (RIGHTS-WRONGS-DON'T KNOWS)	-0.66	-0.15	0.58	0.82	0.73	0.98	2.919	0.014

Note: Scheffe's post-hoc multiple comparisons were used to test differences across formats when the univariate ANOVA was significant at the $p<0.004$ level. An alpha level of 0.004 was used after applying a Bonferroni correction. Groups marked with the same letter do not significantly differ from each other.

Table 41. Differences across formats – Knowledge pertaining to drug benefits

Outcome Measure	No brief summary	Original Brief summary	Risk Information Window	Question Answer Format	Bulleted List format	Nutrition Facts Panel	F	p-value
# of knowledge items on benefits correctly responded	4.66	4.39	4.29	4.39	4.59	4.47		
# of knowledge items on benefits incorrectly responded	0.72	0.78	1.33	0.98	0.92	0.72		
# of knowledge items on benefits responded with a don't know	0.60	0.82	0.37	0.62	0.48	0.80		
Score for drug benefits knowledge scale (RIGHTS-WRONGS-DON'T KNOWS)	3.33	2.78	2.58	2.78	3.19	2.94	0.714	0.614

Note: Scheffe's post-hoc multiple comparisons were used to test differences across formats when the univariate ANOVA was significant at the $p<0.004$ level. An alpha level of 0.004 was used after applying a Bonferroni correction. Groups marked with the same letter do not significantly differ from each other.

Table 42. Differences across formats – Knowledge questionnaire

Outcome Measure	No brief summary	Original Brief summary	Risk Information Window	Question Answer Format	Bulleted List format	Nutrition Facts Panel	F	p-value
# of knowledge items correctly responded	7.33	7.31	7.59	7.80	7.96	7.96		
# of knowledge items incorrectly responded	2.90	2.49	3.25	2.56	2.67	2.39		
# of knowledge items responded with a don't know	1.76	2.20	1.16	1.63	1.37	1.65		
Overall score for knowledge scale (RIGHTS-WRONGS-DON'T KNOWS)	2.66	2.62	3.17	3.60	3.92	3.92	1.017	0.407

Note: Scheffe's post-hoc multiple comparisons were used to test differences across formats when the univariate ANOVA was significant at the $p<0.004$ level. An alpha level of 0.004 was used after applying a Bonferroni correction. Groups marked with the same letter do not significantly differ from each other.

Table 43. Differences across formats – Evaluation of the brief summary

Outcome Measure	Formats			
	Original Brief summary	Question Answer Format	Bulleted List format	Nutrition Facts Panel
Evaluation of brief summary information - READABLE	4.25	5.86	6.25	6.22
Evaluation of brief summary information - CLEAR	4.39	5.78	5.86	6.00
Evaluation of brief summary information - COMPLETE	5.14	5.92	5.90	6.00
Evaluation of brief summary information - ACCURATE	4.80	5.63	5.88	5.86
Evaluation of brief summary information - INFORMATIVE	4.94	5.78	5.86	5.86
Evaluation of brief summary information - UNDERSTANDABLE	4.65	5.73	6.00	6.12
Evaluation of brief summary information - BELIEVABLE	5.16	5.65	5.75	6.04

Table 44. Differences across formats – Attention to the ad

Outcome Measure	No brief summary	Original Brief summary	Risk Information Window	Question Answer Format	Bulleted List format	Nutrition Facts Panel	Test stati-stic	p-value
Time (in seconds) attended the promotional page	60.67	75.53	69.10	56.75	69.90	54.31	2.26[+]	0.048
Time (in seconds) attended the back page brief summary	-	57.16	-	62.06	84.08	46.24	2.89[+]	0.036
% consumers read the back page brief summary without prompting	-	56.8%	-	58.8%	67.3%	66.6%	1.87[^]	0.599

[+] Scheffe's post-hoc multiple comparisons were used to test differences across formats when the univariate ANOVA was significant at the $p<0.05$ level. Groups marked with the same letter do not significantly differ from each other.

[^] A chi-square test of significance was used to test differences across formats on this variable.

Table 45. Differences between prompted and unprompted consumers

Outcome Measure	Mean score		F	p-value
	Looked at brief summary without prompting			
	Yes	No		
Evaluation of quality of risk information	5.78	5.86	0.260	0.610
Evaluation of quality of benefit information	5.86	5.72	0.646	0.422
Evaluation of quality of brief summary	5.65	5.56	0.209	0.648
Ad believability	5.61	5.56	0.089	0.766
Attitudes towards the ad	5.76	5.60	1.608	0.206
Attitudes towards the brand	3.21	5.72	0.057	0.812
Use of ad information in decision-making	5.55	5.70	0.489	0.485
Perceived product risk	3.21	3.72	4.657	0.032

Note: Scheffe's post-hoc multiple comparisons were used to test differences across formats when the univariate ANOVA was significant at the $p<0.006$ level. An alpha level of 0.006 was used after applying a Bonferroni correction. Groups marked with the same letter do not significantly differ from each other.

Table 46. Differences between knowledge of risks and benefits across formats

	n	Mean score		Paired t-test p-value
		Knowledge of drug risks (Range -7 to 7)	Knowledge of drug benefits (Range -7 to 7)	
Overall	305	0.38	2.92	0.000*
No brief summary	51	-0.66	3.33	0.000*
Risk Information Window	50	0.58	2.52	0.000*
Original Brief summary	51	-0.15	2.78	0.000*
Question-Answer Format	51	0.82	2.78	0.000*
Bulleted List format	51	0.73	3.17	0.000*
Nutrition Facts Panel	51	0.98	2.94	0.000*

* Indicates that the paired t-tests were significant. An alpha level of 0.007 was used after applying a Bonferroni correction for the 7 paired t-tests.
Note: Since the paired t-test for all formats grouped together showed that knowledge of risks versus benefits differs significantly, individual paired t-tests were conducted for each format separately.

Table 47. Differences between risk and benefit information across formats

	n	Mean score		Paired t-test p-value
		Evaluation of quality of risk information (Range 1 to 7)	Evaluation of quality of benefit information (Range 1 to 7)	
Overall	305	5.87	5.88	0.719

Note: Since the paired t-test for all formats grouped together showed that evaluation of the quality of risk versus benefit information did not differ significantly, individual paired t-tests were not conducted for each format separately.

Table 48. Path Analysis - Correction for attenuation

Cell - Brief Summary Format	Reliability (α)	Correction for attenuation ($1-\alpha^{1/2}$)
Evaluation of quality of risk information	0.908	0.047
Evaluation of quality of benefit information	0.925	0.038
Ad Believability	0.943	0.029
Perceived product risk	0.915	0.043
Attitude towards the ad	0.870	0.067
Attitude towards the brand	0.898	0.052
Use in health care decision-making	0.934	0.034

Table 49. Path Analysis – Comparison of Model 1 vs. Model 2

Model	χ2	df	p-value	SRMR	CFI	NFI	NNFI	GFI	AGFI	PGFI	PNFI
Model 1	52.57	9	0.000	0.07	0.98	0.97	0.96	0.94	0.87	0.40	0.58
Model 2	90.01	13	0.000	0.09	0.97	0.96	0.94	0.93	0.84	0.43	0.59

Model Comparison	Δχ2	Δdf	p-value	ΔSRMR	ΔCFI	ΔNFI	ΔNNFI	ΔGFI	ΔAGFI	ΔPGFI	ΔPNFI
Model 1 vs. Model 2	37.44	4	0.000	0.02	0.01	0.01	0.02	0.01	0.03	0.03	0.01

Note: χ2 = Chi-square goodness-of-fit test
df = Degrees of freedom
SRMR = Standardized Root Mean Residual
CFI = Comparative Fit Index
NFI = Normed Fit Index
NNFI = Non-Normed Fit Index
GFI = Goodness of Fit Index
AGFI = Adjusted Goodness of Fit Index
PGFI = Parsimony Goodness of Fit Index
PNFI = Parsimony Normed Fit Index

Table 50. Path Analysis – Parameter estimates of Model 1

Dependent Variable	R^2	Predictors	Std. Path Coefficients	Unstd. Path Coefficients	Std. Error	t-value
Ad believability	0.57	Evaluation of quality of risk information	0.43	0.45	0.009	4.95*
		Evaluation of quality of benefit information	0.35	0.36	0.009	4.02*
Attitude towards the ad	0.37	Ad believability	0.80	0.83	0.04	21.29*
Attitude towards the brand	0.26	Attitude towards the ad	0.84	0.90	0.04	23.97*
Use of ad information in decision-making	0.19	Attitude towards the ad	0.72	0.90	0.05	17.08*

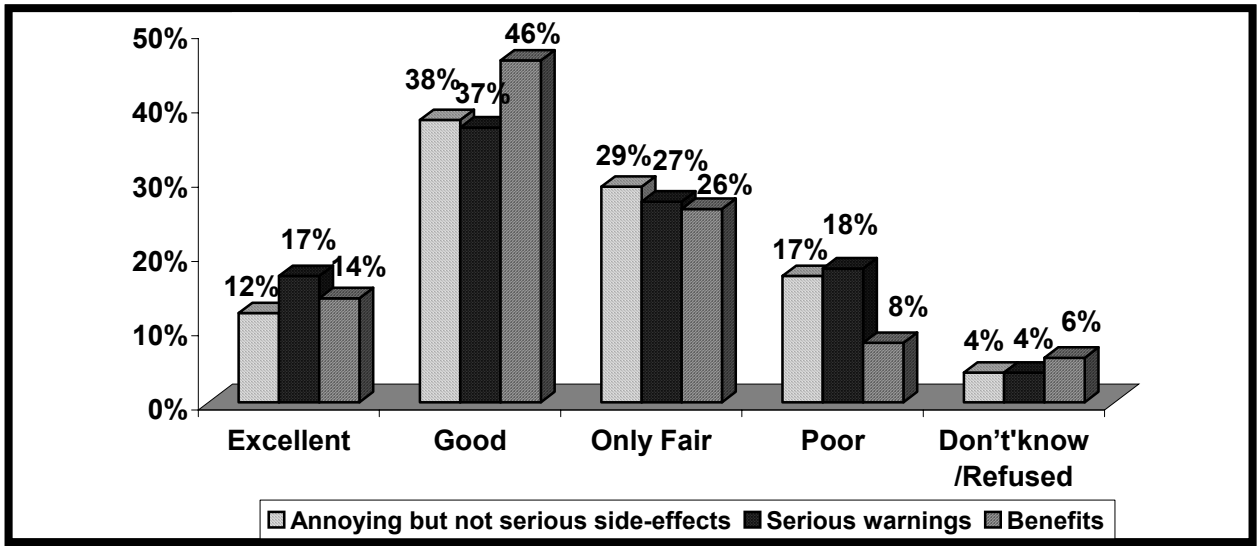
* Path coefficients are statistically significant at $p<0.01$

Table 51. Path Analysis – Parameter estimates of Model 2

Dependent Variable	R^2	Predictors	Std. Path Coefficients	Unstd. Path Coefficients	Std. Error	t-value
Ad believability	0.57	Evaluation of quality of risk information	0.44	0.46	0.09	5.09*
		Evaluation of quality of benefit information	0.34	0.35	0.09	3.88*
Perceived Product Risk	0.13	Evaluation of quality of risk information	- 0.36	- 0.51	0.08	- 6.42*
Attitude towards the ad	0.36	Ad believability	0.80	0.83	0.04	21.00*
Attitude towards the brand	0.28	Perceived Product Risk	- 0.13	- 0.11	0.03	- 3.78*
		Attitude towards the ad	0.80	0.84	0.04	22.12*
Use of ad information in decision-making	0.19	Attitude towards the ad	0.72	0.89	0.05	16.80*

* Path coefficients are statistically significant at $p<0.01$

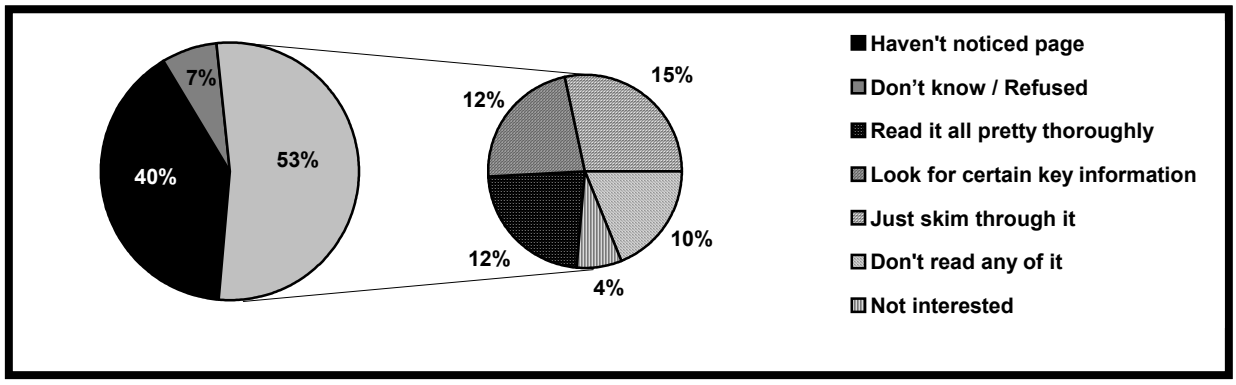
FIGURES



Based on the question from Prevention survey 2001, *"We'd like your opinions of the job that advertisements for prescription drugs do in providing certain kinds of information. How would you rate the job they do in providing information about……?"* Based on consumers who reported seeing/hearing a DTC ad (n=1582)

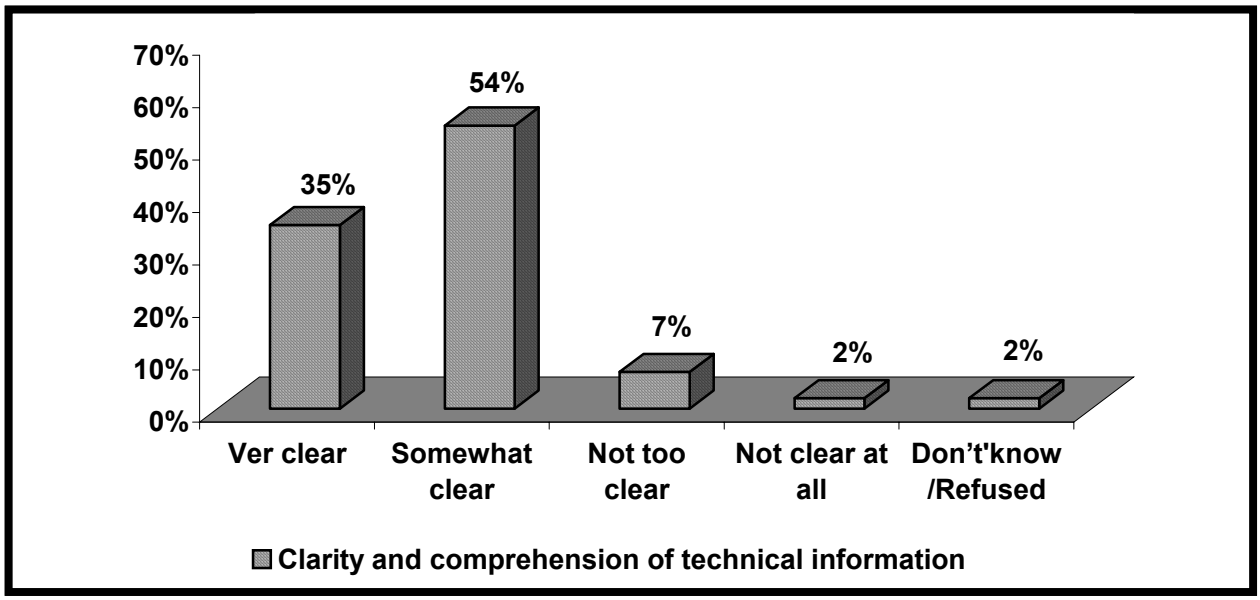
Figure 7. Consumers' Evaluation of the risk and benefit Information in DTC ads

(Source: Prevention 2001)



Based on the question from Prevention survey 1999, *"In magazine advertisements for prescription medicines, technical information about the risks of taking the product is included with the ad as an additional page of plain black and white print. Have you ever noticed this technical information before, or not……. How much of the technical information page do you usually read?"* Based on consumers who reported seeing magazine DTC ads (n=689)

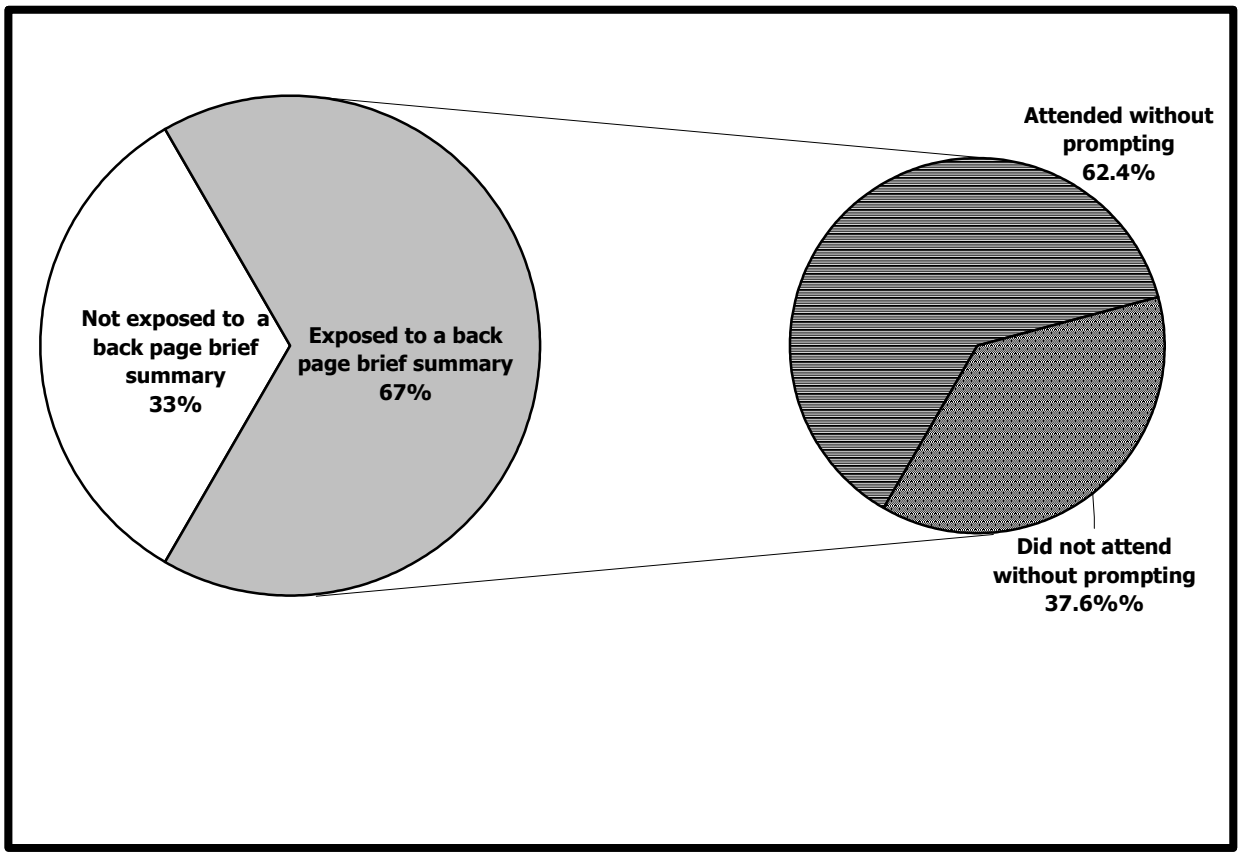
Figure 8. Consumers' Interaction with the brief summary in DTC ads (Source: Prevention 1999)



Based on the question from Prevention survey 1999, *"In general, how clear and understandable is the information you are looking for on the technical information page?"* Based on consumers who reported reading the technical page in DTC ads (n=279)

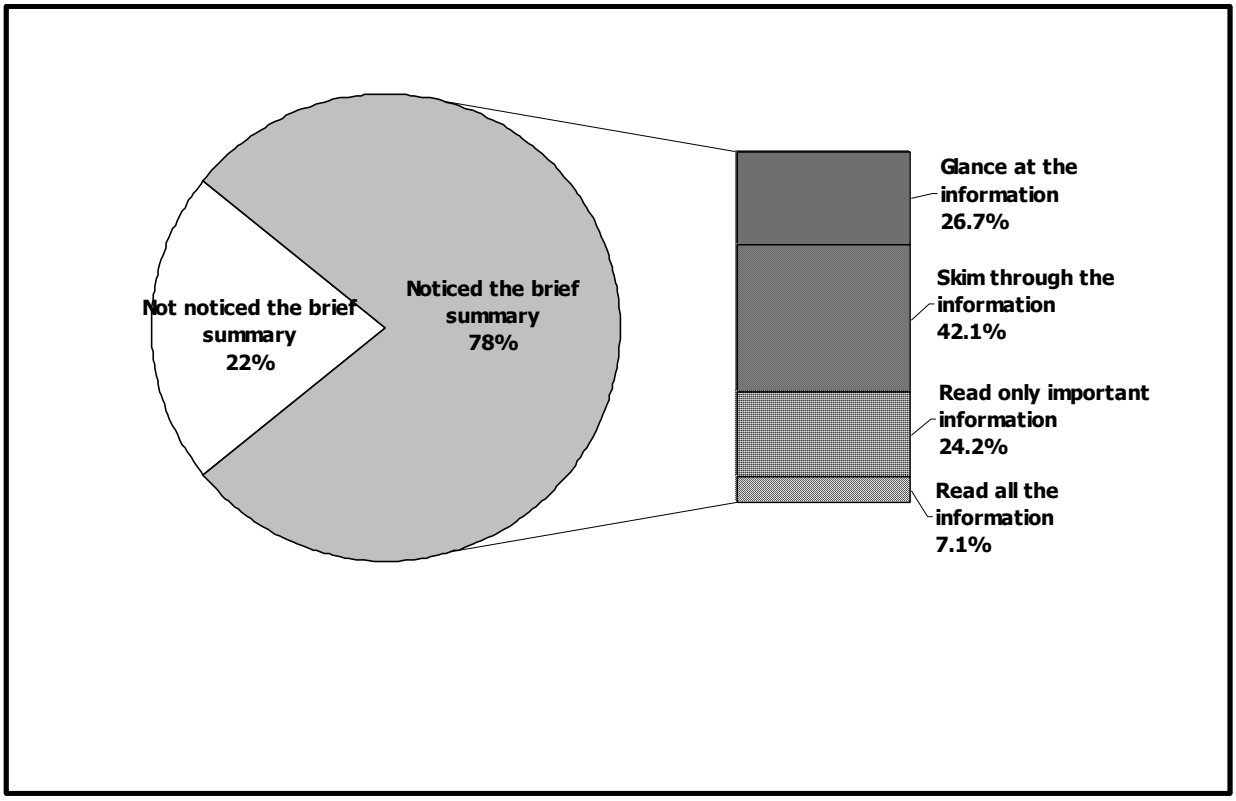
Figure 9. Consumers' Evaluation of the brief summary in DTC ads

(Source: Prevention 1999)



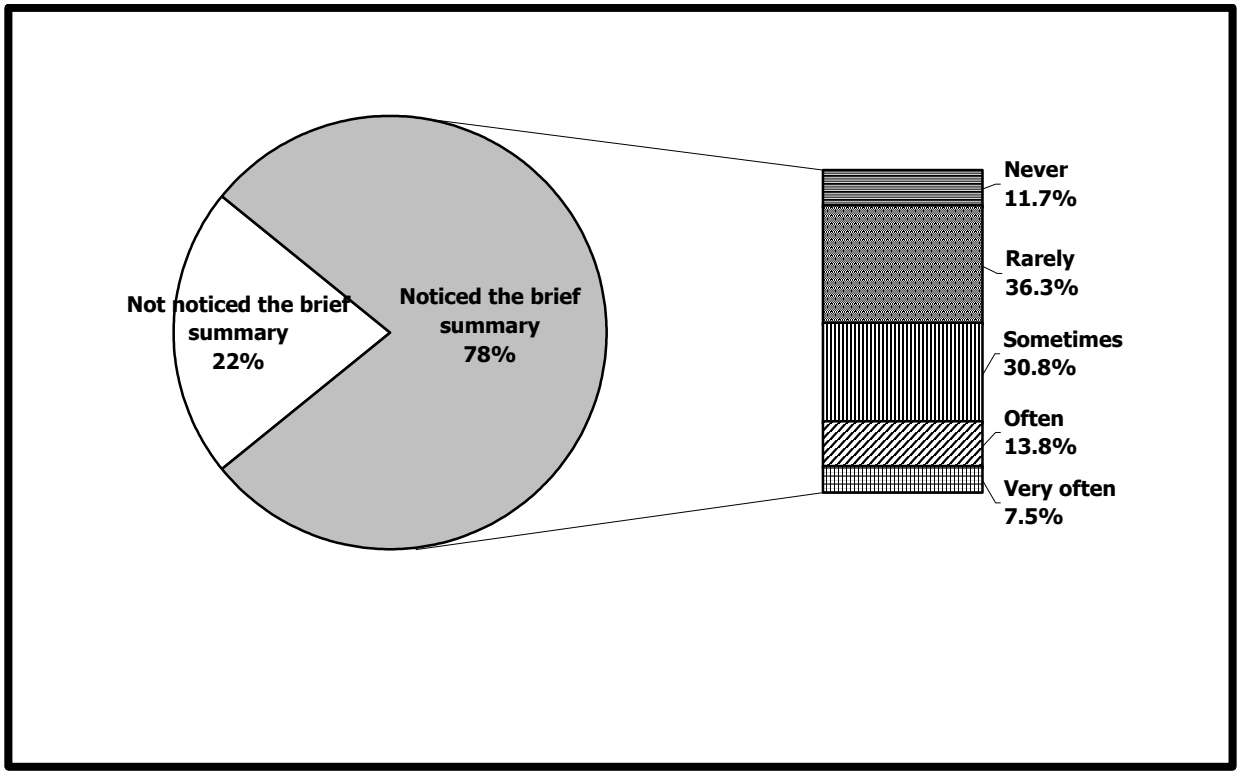
Based on all consumers in the study n=307

Figure 10. Attention to the brief summary in the quantitative experiment



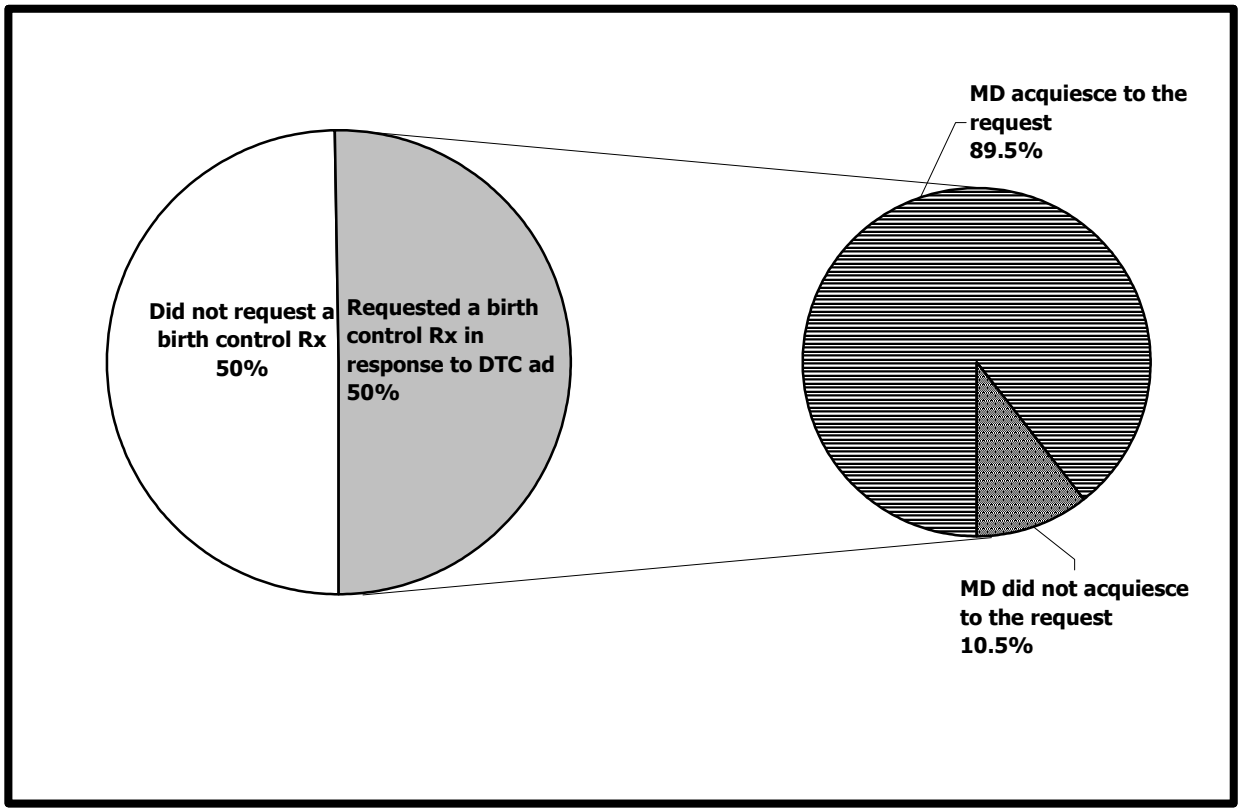
Based on all consumers in the study n=307

Figure 11. Amount of attention paid to the brief summary in the past



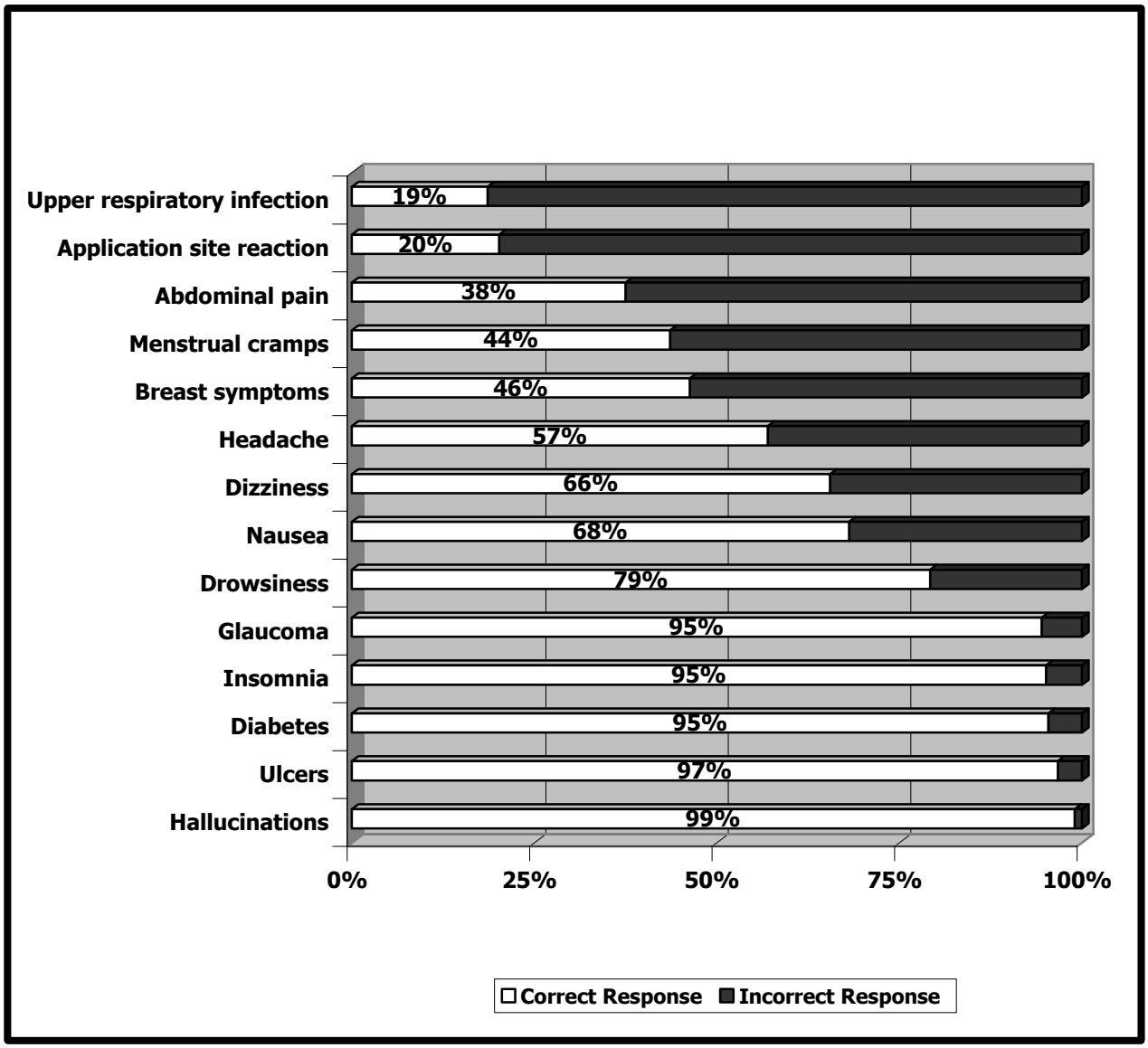
Based on all consumers in the study n=307

Figure 12. Frequency of attention to the brief summary in the past



Based on all consumers in the study n=307

Figure 13. Consumers' past drug requests and physician acquiescence



Based on all consumers in the study n=307

Figure 14. Consumers' responses to the adverse drug reaction questionnaire

APPENDIX

Appendix A: Survey Instrument for ads without a Brief Summary

College of Pharmacy

Prescription Drug Advertising Survey

Please look carefully at the advertisement for OrthoEvra® - a prescription medicine. **ASSUME THAT THIS IS A PRESCRIPTION MEDICINE YOU ARE INTERESTED IN USING.** After looking at the ad, please answer the following questions.

Time looked at the FRONT PAGE of the ad: _____

Instructions: Please answer the following questions by placing and 'X' in the space that best reflects how you feel. For example, if the question is "How is the weather today?" and you feel that the weather is extremely good, then you would place the 'X' as follows:

Good	X 1	2	3	4	5	6	7	Bad

Please place your 'X' in the middle of the spaces.

Section 1: Please answer the following questions based on the OrthoEvra® ad you just read. Which of the following side effects commonly occur when using OrthoEvra®? Please ☑ all those apply.

- ☐ Breast symptoms
- ☐ Glaucoma
- ☐ Ulcers
- ☐ Headache
- ☐ Application site reaction
- ☐ Nausea
- ☐ Dizziness
- ☐ Hallucinations
- ☐ Menstrual cramps
- ☐ Upper respiratory infection
- ☐ Insomnia
- ☐ Drowsiness
- ☐ Diabetes
- ☐ Abdominal pain

<u>Section 2:</u> Please answer the following questions based on the OrthoEvra® ad you just read. Please ☑ ONLY the best response. If the information necessary to answer the question is not in the ad or you are not sure, please ☑ the Don't know/Not sure option.

1) **This product protects against HIV infection (AIDS) and other sexually transmitted diseases.**
   - □ True
   - □ False
   - □ Don't know/Not sure

2) **The safety and effectiveness of OrthoEvra® patch is better than a birth control pill.**
   - □ True
   - □ False
   - □ Don't know/Not sure

3) **The OrthoEvra® patch is _____ effective. (☑ 1 option)**
   - □ 95%
   - □ 98%
   - □ 99%
   - □ Don't know/Not sure

4) **The OrthoEvra® patch should be changed _____ (☑ 1 option)**
   - □ Once a day
   - □ Once a week
   - □ Once a month
   - □ Don't know/Not sure

5) **OrthoEvra® should be used with caution in water (e.g. while swimming).**
   - □ True
   - □ False
   - □ Don't know/Not sure

6) **The OrthoEvra® patch is safe for use in emergency contraception.**
   - □ True
   - □ False
   - □ Don't know/Not sure

7) **_____ increases the risks of having side effects with OrthoEvra®. (☑ 1 option)**
   - □ Alcohol use
   - □ Smoking
   - □ Exercise
   - □ Don't know/Not sure

8) **The use of OrthoEvra® increases the risk of several conditions like _____ (☑ 1 option)**
   - □ Blood Clots
   - □ Skin Cancer
   - □ Coma
   - □ Osteoporosis
   - □ Don't know/Not sure

9) **Overdosage of OrthoEvra® causes _____ (☑ 1 option)**
   - □ Cancer
   - □ Nausea and Vomiting
   - □ Abdominal pain
   - □ Diabetes
   - □ Don't know/Not sure

10) OrthoEvra® should be used with caution by women who _____(☑ 1 option)

- □ Suffer from Osteoporosis
- □ Suffer from psoriasis and other skin conditions
- □ Wear contact lenses
- □ Consume alcohol
- □ Don't know/Not sure

11) OrthoEvra® can be safely used during breast feeding/nursing.

- □ True
- □ False
- □ Don't know/Not sure

12) Women _____ should not use OrthoEvra® (☑ only 1 option)

- □ Over age 35
- □ Under age 18
- □ Athletes
- □ With family history of breast cancer
- □ Don't know/Not sure

<u>Section 3:</u> Now, think only about the information in the ad regarding the <u>RISKS</u> of OrthoEvra®. Please place an "X" on the space in the questionnaire that best reflects how you feel about the <u>RISK</u> information.

Readable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unreadable
Clear	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unclear
Complete	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Incomplete
Accurate	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Inaccurate
Informative	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not informative
Understandable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not understandable
Believable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unbelievable

<u>Section 4:</u> Now, think only about the information in the ad regarding the <u>BENEFITS</u> of OrthoEvra®. Please place an "X" on the space in the questionnaire that best reflects how you feel about the <u>BENEFIT</u> information.

Readable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unreadable

Clear	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unclear
Complete	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Incomplete
Accurate	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Inaccurate
Informative	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not informative
Understandable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not understandable
Believable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unbelievable

<u>Section 5:</u> Now, think about the entire OrthoEvra® ad. How believable was this ad? Please place an "X" on the space in the questionnaire that best reflects how you feel about the <u>BELIEVABILITY</u> of this ad.

Believable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unbelievable
Trustworthy	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Untrustworthy
Convincing	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not convincing
Credible	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not credible
Reasonable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unreasonable
Honest	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Dishonest
Unquestionable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Questionable
Conclusive	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Inconclusive
Authentic	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not authentic
Likely	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unlikely

<u>Section 6</u>: Below you will find a list of descriptions that represent different feelings about the advertisement that you just read. Please place an "X" on the space in the questionnaire that best reflects how you feel about this ad.

Good	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Bad
Pleasant	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unpleasant
Favorable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unfavorable

<u>Section 7</u>: Below you will find a list of descriptions that represent different feelings about the OrthoEvra® brand that you just read about. Please place an "X" on the space in the questionnaire that best reflects how you feel about this brand.

Good	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Bad
Positive	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Negative
Favorable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unfavorable

<u>Section 8</u>: Assume you are interested in using birth control. How likely are you to use the information in this ad to make a decision about whether the OrthoEvra® patch is right for you. Please place an "X" on the space in the questionnaire that best reflects how you feel.

Likely	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unlikely
Probable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Improbable
Possible	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Impossible

<u>Section 9</u>: Now, think about the risks and side effects of OrthoEvra®. Please place an "X" on the space in the questionnaire that best reflects how you feel about the riskiness of OrthoEvra®.

1) How dangerous do you think OrthoEvra® is for you?

Very dangerous	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not at all dangerous

2) How would you feel about using OrthoEvra® yourself?

Very afraid	1	2	3	4	5	6	7	Not at all afraid

3) If you were to use this drug, how likely do you think you would be to suffer from OrthoEvra®'s side effects?

Very likely	1	2	3	4	5	6	7	Not at all likely

4) How do you think the benefits of using OrthoEvra® compare to the risks?

Greater Risks	1	2	3	4	5	6	7	Greater benefits

5) How risky is it for you to use OrthoEvra®?

Very risky	1	2	3	4	5	6	7	Not at all risky

<u>Section 10</u>: Now, we would like to learn about your experience with ads for prescription medications.

1) In general, how frequently do you read magazines? Please ☑ only one option.

- ☐ Never
- ☐ Once a month
- ☐ Once a week
- ☐ 2-3 times a week
- ☐ Greater than 3 times a week

2) Which of these magazines have you read in the past 1 year? Please ☑ all that apply.

- ☐ Ladies Home Journal
- ☐ Self
- ☐ Cosmopolitan
- ☐ Good Housekeeping
- ☐ Prevention

3) In the past, have you read/seen advertisements for prescription drugs in magazines?

- ☐ Yes
- ☐ No

4) Generally, ads for prescription medications in magazines have a technical page containing risk and side effect information about the drug on the reverse side. Have you ever noticed this page?

- ☐ Yes
- ☐ No

4a) If you ☑ yes, which of the following do you usually do, when you notice this technical page on the reverse side of the ad? Please ☑ only one option.

- ☐ Glance at the information
- ☐ Skim through the information
- ☐ Read information that you think is important
- ☐ Read all the information very thoroughly

4b) How often do you read this technical page on the reverse side of an ad for a drug you are interested in taking? Please ☑ one option.

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Very often

5) Are you currently taking any prescription medication for birth control?

- ☐ Yes
- ☐ No

6) Which of the following types of prescription birth control medications have you used? Please ☑ all that apply.

- ☐ Patch
- ☐ Pill
- ☐ Ring

7) In the past, which of the following prescription birth control medications have you seen/heard advertised? Please ☑ all that apply.

- ☐ Yasmin®
- ☐ Ortho-Tricyclen®
- ☐ Contracept®
- ☐ OrthoEvra®
- ☐ Seasonale®

8) In the past, have you ever asked your doctor for a prescription birth control medication that you have seen/heard advertised?

- ☐ Yes
- ☐ No

8a) If you ☑ yes, did your doctor prescribe the medication you requested?

- ☐ Yes
- ☐ No

<u>Section 11</u>: Finally, just a few questions about you. This information is for descriptive purposes only.

1) How do you describe yourself? (Specify mixed racial heritage by ☑ more than one option).

- ☐ American Indian or Alaska native
- ☐ Asian
- ☐ Black or African-American
- ☐ Hispanic or Latino
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White

2) Which of the following categories best describes your age?

- ☐ 18-20 yrs
- ☐ 21-25 yrs
- ☐ 26-30 yrs
- ☐ 31-35 yrs
- ☐ 36-45 yrs
- ☐ 46-50 yrs

3) What is the highest level of education you have completed?

- ☐ Less than high school
- ☐ High school graduate or equivalent (e.g. GED)
- ☐ Associates/Technical/Vocational degree
- ☐ Completed some part of college, but no degree
- ☐ College graduate
- ☐ Graduate school or higher

Thank you very much for your time. Your participation has been very valuable and helpful

****

Appendix B. Survey Instrument for ads with a Brief Summary

College of Pharmacy

Prescription Drug Advertising Survey

Please look carefully at the advertisement for OrthoEvra® - a prescription medicine. **ASSUME THAT THIS IS A PRESCRIPTION MEDICINE YOU ARE INTERESTED IN USING.** After looking at the ad, please answer the following questions.

Time looked at the FRONT PAGE of the ad: _____

Time looked at the BACK PAGE of the ad: _____ (Looked at page without prompting: **YES / NO**)

Instructions: Please answer the following questions by placing and 'X' in the space that best reflects how you feel. For example, if the question is "How is the weather today?" and you feel that the weather is extremely good, then you would place the 'X' as follows:

Good	X							Bad
	1	2	3	4	5	6	7	

Please place your 'X' in the middle of the spaces.

Section 1: Please answer the following questions based on the OrthoEvra® ad you just read. Which of the following side effects commonly occur when using OrthoEvra®? Please ☑ all those apply.

- ☐ Breast symptoms
- ☐ Glaucoma
- ☐ Ulcers
- ☐ Headache
- ☐ Application site reaction
- ☐ Nausea
- ☐ Dizziness
- ☐ Hallucinations
- ☐ Menstrual cramps
- ☐ Upper respiratory infection
- ☐ Insomnia
- ☐ Drowsiness
- ☐ Diabetes
- ☐ Abdominal pain

<u>Section 2:</u> Please answer the following questions based on the OrthoEvra® ad you just read. Please ☑ ONLY the best response. If the information necessary to answer the question is not in the ad or you are not sure, please ☑ the Don't know/Not sure option.

1) This product protects against HIV infection (AIDS) and other sexually transmitted diseases.
- □ True
- □ False
- □ Don't know/Not sure

2) The safety and effectiveness of OrthoEvra® patch is better than a birth control pill.
- □ True
- □ False
- □ Don't know/Not sure

3) The OrthoEvra® patch is _____ effective. (☑ 1 option)
- □ 95%
- □ 98%
- □ 99%
- □ Don't know/Not sure

4) The OrthoEvra® patch should be changed _____ (☑ 1 option)
- □ Once a day
- □ Once a week
- □ Once a month
- □ Don't know/Not sure

5) OrthoEvra® should be used with caution in water (e.g. while swimming).
- □ True
- □ False
- □ Don't know/Not sure

6) The OrthoEvra® patch is safe for use in emergency contraception.
- □ True
- □ False
- □ Don't know/Not sure

8) _____ increases the risks of having side effects with OrthoEvra®. (☑ 1 option)
- □ Alcohol use
- □ Smoking
- □ Exercise
- □ Don't know/Not sure

9) The use of OrthoEvra® increases the risk of several conditions like _____ (☑ 1 option)
- □ Blood Clots
- □ Skin Cancer
- □ Coma
- □ Osteoporosis
- □ Don't know/Not sure

9) Overdosage of OrthoEvra® causes _____ (☑ 1 option)
- □ Cancer
- □ Nausea and Vomiting
- □ Abdominal pain
- □ Diabetes
- □ Don't know/Not sure

10) OrthoEvra® should be used with caution by women who _____(☑ 1 option)

- □ Suffer from Osteoporosis
- □ Suffer from psoriasis and other skin conditions
- □ Wear contact lenses
- □ Consume alcohol
- □ Don't know/Not sure

11) OrthoEvra® can be safely used during breast feeding/nursing.

- □ True
- □ False
- □ Don't know/Not sure

12) Women _____ should not use OrthoEvra® (☑ 1 option)

- □ Over age 35
- □ Under age 18
- □ Athletes
- □ With family history of breast cancer
- □ Don't know/Not sure

<u>Section 3:</u> Now, think only about the information in the ad regarding the <u>RISKS</u> of OrthoEvra®. Please place an "X" on the space in the questionnaire that best reflects how you feel about the <u>RISK</u> information.

Readable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unreadable
Clear	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unclear
Complete	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Incomplete
Accurate	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Inaccurate
Informative	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not informative
Understandable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not understandable
Believable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unbelievable

<u>Section 4:</u> Now, think only about the information in the ad regarding the <u>BENEFITS</u> of OrthoEvra®. Please place an "X" on the space in the questionnaire that best reflects how you feel about the <u>BENEFIT</u> information.

Readable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unreadable

Clear	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unclear
Complete	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Incomplete
Accurate	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Inaccurate
Informative	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not informative
Understandable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not understandable
Believable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unbelievable

<u>Section 5:</u> Now, think only about the <u>TECHNICAL PAGE</u> on the reverse side of the ad that contains information about the risks and side effects of the drug. Please place an "X" on the space in the questionnaire that best reflects how you feel about the <u>TECHNICAL PAGE</u>.

Readable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unreadable
Clear	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unclear
Complete	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Incomplete
Accurate	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Inaccurate
Informative	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not informative
Understandable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not understandable
Believable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unbelievable

<u>Section 6:</u> Now, think about the entire OrthoEvra® ad. How believable was this ad? Please place an "X" on the space in the questionnaire that best reflects how you feel about the <u>BELIEVABILITY</u> of this ad.

Believable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unbelievable

Trustworthy	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Untrustworthy
Convincing	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not convincing
Credible	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not credible
Reasonable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unreasonable
Honest	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Dishonest
Unquestionable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Questionable
Conclusive	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Inconclusive
Authentic	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not authentic
Likely	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unlikely

<u>Section 7</u>: Below you will find a list of descriptions that represent different feelings about the advertisement that you just read. Please place an "X" on the space in the questionnaire that best reflects how you feel about this ad.

Good	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Bad
Pleasant	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unpleasant
Favorable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unfavorable

<u>Section 8</u>: Below you will find a list of descriptions that represent different feelings about the OrthoEvra® brand that you just read about. Please place an "X" on the space in the questionnaire that best reflects how you feel about this brand.

Good	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Bad
Positive	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Negative

Favorable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unfavorable

<u>Section 9</u>: Assume you are interested in using birth control. How likely are you to use the information in this ad to make a decision about whether the OrthoEvra® patch is right for you. Please place an "X" on the space in the questionnaire that best reflects how you feel.

Likely	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Unlikely
Probable	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Improbable
Possible	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Impossible

<u>Section 10</u>: Now, think about the risks and side effects of OrthoEvra®. Please place an "X" on the space in the questionnaire that best reflects how you feel about the riskiness of OrthoEvra®.

1) How dangerous do you think OrthoEvra® is for you?

Very dangerous	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not at all dangerous

2) How would you feel about using OrthoEvra® yourself?

Very afraid	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not at all afraid

3) If you were to use this drug, how likely do you think you would be to suffer from OrthoEvra®'s side effects?

Very likely	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not at all likely

4) How do you think the benefits of using OrthoEvra® compare to the risks?

Greater Risks	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Greater benefits

5) How risky is it for you to use OrthoEvra®?

Very risky	_____ 1	_____ 2	_____ 3	_____ 4	_____ 5	_____ 6	_____ 7	Not at all risky

<u>Section 11</u>: Now, we would like to learn about your experience with ads for prescription medications.

1) In general, how frequently do you read magazines? Please ☑ only one option.

- ☐ Never
- ☐ Once a month
- ☐ Once a week
- ☐ 2-3 times a week
- ☐ Greater than 3 times a week

2) Which of these magazines have you read in the past 1 year? Please ☑ all that apply.

- ☐ Ladies Home Journal
- ☐ Self
- ☐ Cosmopolitan
- ☐ Good Housekeeping
- ☐ Prevention

3) In the past, have you read/seen advertisements for prescription drugs in magazines?

- ☐ Yes
- ☐ No

4) Generally, ads for prescription medications in magazines have a technical page containing risk and side effect information about the drug on the reverse side. Have you ever noticed this page?

- ☐ Yes
- ☐ No

4a) If you ☑ yes, which of the following do you usually do, when you notice this technical page on the reverse side of the ad? Please ☑ only one option.

- ☐ Glance at the information
- ☐ Skim through the information
- ☐ Read information that you think is important
- ☐ Read all the information very thoroughly

4b) How often do you read this technical page on the reverse side of an ad for a drug you are interested in taking? Please ☑ one option.

- ☐ Never
- ☐ Rarely
- ☐ Sometimes
- ☐ Often
- ☐ Very often

5) Are you currently taking any prescription medication for birth control?

- ☐ Yes
- ☐ No

6) Which of the following types of prescription birth control medications have you used? Please ☑ all that apply.

- ☐ Patch
- ☐ Pill
- ☐ Ring

7) In the past, which of the following prescription birth control medications have you seen/heard advertised? Please ☑ all that apply.

- ☐ Yasmin®
- ☐ Ortho-Tricyclen®
- ☐ Contracept®
- ☐ OrthoEvra®
- ☐ Seasonale®

8) In the past, have you ever asked your doctor for a prescription birth control medication that you have seen/heard advertised?

- ☐ Yes
- ☐ No

8a) If you ☑ yes, did your doctor prescribe the medication you requested?

- ☐ Yes
- ☐ No

<u>Section 12</u>: Finally, just a few questions about you. This information is for descriptive purposes only.

1) How do you describe yourself? (Specify mixed racial heritage by ☑ more than one option).

- ☐ American Indian or Alaska native
- ☐ Asian
- ☐ Black or African-American
- ☐ Hispanic or Latino
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ White

2) Which of the following categories best describes your age?

- 18-20 yrs
- 21-25 yrs
- 26-30 yrs
- 31-35 yrs
- 36-45 yrs
- 46-50 yrs

3) What is the highest level of education you have completed?

- Less than high school
- High school graduate or equivalent (e.g. GED)
- Associates/Technical/Vocational degree
- Completed some part of college, but no degree
- College graduate
- Graduate school or higher

Thank you very much for your time. Your participation has been very valuable and helpful

****

Appendix C. Consent Form for the Focus Groups

I, _____, agree to participate in a research study titled **"An Investigation of Consumers' Information Processing from Print Direct-to-Consumer Advertisements"** conducted by Aparna Deshpande, from the College of Pharmacy at the University of Georgia (706-542-0418) under the direction of Dr. Matthew Perri III, College of Pharmacy, University of Georgia (706-542-5365). I understand that my participation is voluntary. 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 this study is to measure consumers' attitudes towards the advertising of prescription medications to determine how to make these ads more consumer-friendly.

If I volunteer to take part in this study, I will be asked to do the following things:

1. Read an advertisement for a prescription medication.
2. Talk about my opinions about the quality of the information presented in the ad

I will receive a $25 Wal-Mart gift card for my participation in this study. The study will take approximately 90 minutes to complete. During the study, the researcher will audio-tape the conversation, however the tapes will be completely confidential. We will retain the tapes for a 3-4 week period during which only the researchers will have access to them. After transcribing the contents of the tapes, they will be erased. We do not expect the subjects to experience any psychological, social, legal, economic or physical discomfort, stress, harm or benefit as a result of participation in this research study. The investigator will answer any further questions about the research, now or during the course of the project (706-542-0418).

I understand that I am agreeing by my signature on this form to take part in this research project and understand that I will receive a signed copy of this consent form for my records.

_____	_____	_____	_____
Signature	**Date**	**Signature**	**Date**

Aparna Deshpande, B.S. (Pharmacy), PhD Candidate
R.C. Wilson Pharmacy Building,
University of Georgia, Athens, GA 30602
Phone: (706) 5420418; Email: deshpana@rx.uga.edu

Matthew Perri III, PhD, R.Ph
R.C. Wilson Pharmacy Building,
University of Georgia, Athens, GA 30602
Phone: (706) 5425365; Email: mperri@rx.uga.edu

_____	_____	_____
Name of Participant	**Signature of Participant**	**Date**

Additional questions or problems regarding your rights as a research participant should be addressed to 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

Appendix D. Cover Letter for the Main Study

Dear Study participant,

This research study is titled **"An Investigation of Consumers' Information Processing from Print Direct-to-Consumer Advertisements"** and is being conducted by Aparna Deshpande, from the College of Pharmacy at the University of Georgia (706-542-0418) under the direction of Dr. Matthew Perri III, College of Pharmacy, University of Georgia (706-542-5365). Participation in this study is voluntary. Participation in this study can be ended at any time without giving any reason, and without penalty. You can ask to have all of the information about you returned to you, removed from the research records, or destroyed.

The reason for this study is to measure consumers' attitudes towards the advertising of prescription medications to determine how to make these ads more consumer-friendly.

You will be asked to do the following things:

3. Read an advertisement for a prescription medication Ortho Evra®. (3 minutes)
4. Fill out a survey questionnaire measuring your perceptions toward the advertisement and demographic characteristics. (7-10 minutes)

In order to make this study a valid one; some information about your participation will be withheld until the completion of the study.

The study will take approximately 12 minutes to complete. The survey will be completely anonymous. The investigator will answer any further questions about the research, now or during the course of the project (706-542-0418).

Please retain this information sheet for your records.

_____	_____	_____	_____
Signature	**Date**	**Signature**	**Date**

Aparna Deshpande, B.S. (Pharmacy), PhD Candidate
R.C. Wilson Pharmacy Building,
University of Georgia, Athens, GA 30602
Phone: (706) 5420418; deshpana@rx.uga.edu

Matthew Perri III, PhD, R.Ph
R.C. Wilson Pharmacy Building,
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Appendix E. Debriefing Statement for the Focus Groups and the Main Study

Dear Study participant,

The prescription medication OrthoEvra® is a real product. However, the technical page of information, on the reverse side of the ad shown to you, was designed by the researchers. The presentation format of the original technical page was changed. The intention of this study was to determine which format works best at conveying prescription drug information.

Thank you once again for your participation in the study.

Signature	**Date**	**Signature**	**Date**

Aparna Deshpande, B.S. (Pharmacy), PhD Candidate
R.C. Wilson Pharmacy Building,
University of Georgia, Athens, GA 30602
Phone: (706) 5420418; deshpana@rx.uga.edu

Matthew Perri III, PhD, R.Ph
R.C. Wilson Pharmacy Building,
University of Georgia, Athens, GA 30602
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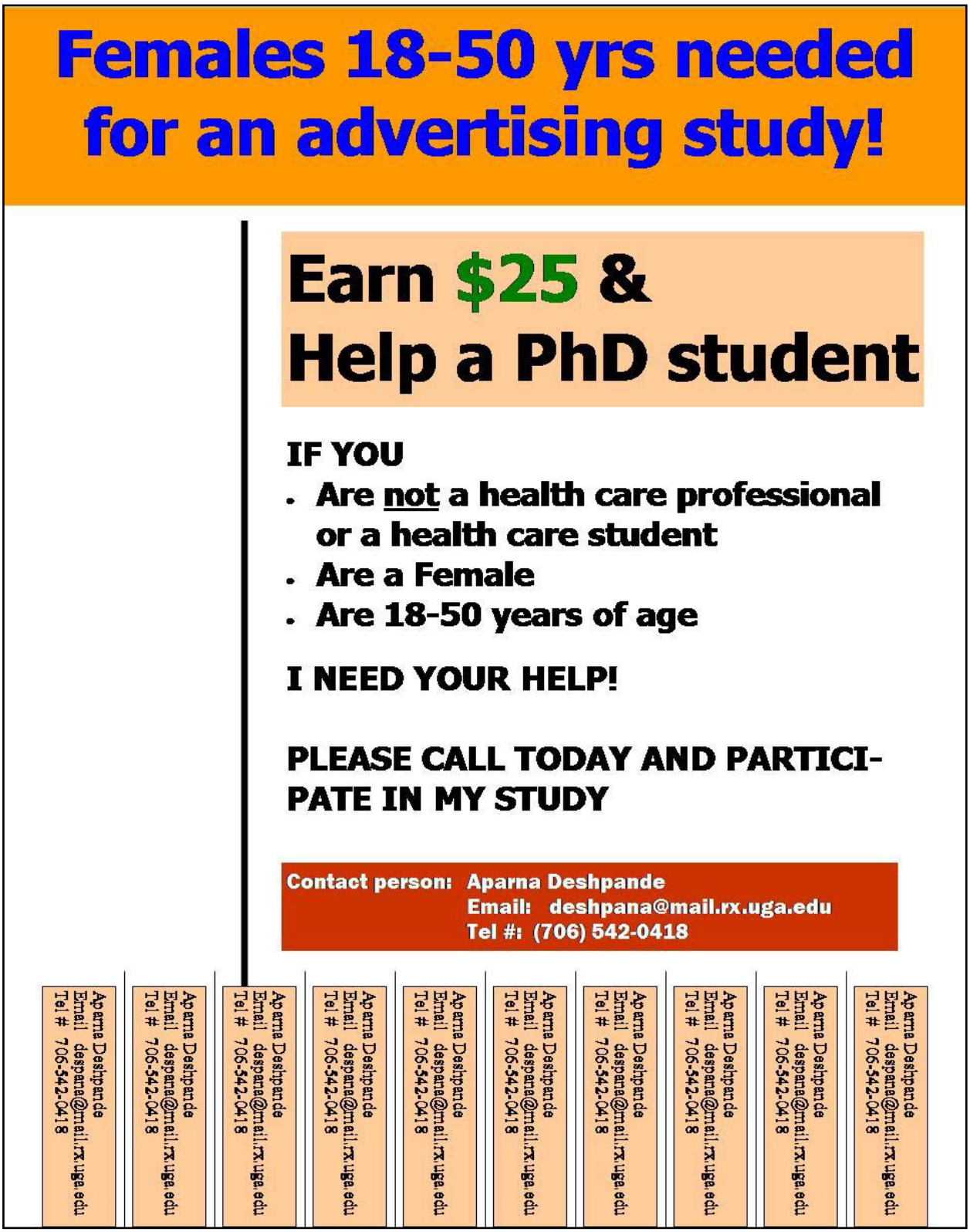
Additional questions or problems regarding your rights as a research participant should be addressed to Chris A. Joseph, Ph.D. Human Subjects Office, University of Georgia, 606A Boyd Graduate Studies Research Center, Athens, Georgia 30602-7411; Telephone (706) 542-3199; E-Mail Address IRB@uga.edu

Appendix F. Recruitment Flyer for the Focus Groups



Appendix G. Interviewer Training Sheet for the Main Study

Prescription Drug Advertising Interviews

<u>STEP 1:</u> RECRUIT PARTCIPANTS

Participants should be

1) Female AND
2) Between 18 years and 50 years of age

We must have at least some representation from minorities like African-Americans and Hispanics

<u>STEP 2:</u> GIVE THEM THE COVER LETTER

<u>STEP3:</u> SHOW THEM THE AD

Please take participants to a quiet room and interview them using paper pencil survey. Randomly assign participants to one of 6 cells and show them the ad in that cell.

The ads in each of the surveys are different

1) White colored surveys – **No** back page
2) Cream colored surveys – **No** back page
3) Blue colored surveys – **Has** back page
4) Grey colored surveys – **Has** back page
5) Lighter Yellow colored surveys – **Has** back page
6) Darker Yellow colored surveys – **Has** back page

<u>STEP 4:</u> RECORD TIME TAKEN BY PARTICIPANT TO READ FRONT PAGE and BACK PAGE SEPARATELY

Inform participants that question will be asked about the information in the ad and they should read the ad as though it were for a product they were extremely interested in using.

For white and cream colored surveys

- Record time taken to read the front page

For blue, grey, light and dark yellow surveys

- Record time taken to read the front page.
- Record if the participants turned the page over themselves to see the back page.
- If they do not read the back page ask them to read it.
- Record time taken to read the back page.

<u>STEP 5:</u> TAKE THE AD AWAY AND DO NOT SHOW THEM THE AD AGAIN

<u>STEP 6:</u> RECORD THEIR RESPONSES TO SURVEY QUESTIONS

<u>STEP 7:</u> HAND THEM THE DEBRIEFING STATEMENT

Thank you for your help with this study

Appendix H. Focus Group Topic Guide

INTRODUCTION

Hello everyone. My name is Aparna Deshpande and I am a graduate student at the College of Pharmacy. Welcome and thank you for participating in this study entitled "An Investigation of Consumers' Information Processing from Print Direct-to-Consumer Advertisements". This study is a part of my doctoral dissertation research.

The study will take approximately 90 minutes to complete and you will be compensated for your time with a $25 Wal-Mart gift certificate. During the study, I will audio-tape the conversation; however the content of the tapes will be completely confidential. No one except the researchers working on this project will have access to these tapes.

Before we begin, I want to give you a brief description of the study and I need you to sign an informed consent of your participation in the study. Direct-to-Consumer ads or DTC ads are prescription drug ads, which you may have seen on TV or in magazines. These ads advertise the prescription drug directly to consumers. We are interested in getting your thoughts and opinions on the information that is conveyed in these ads. For the purpose of this study we will be examining an ad for a prescription medication called OrthoEvra, which is a birth-control patch.

Now, please read the OrthoEvra ad completely, as if it is a product you are interested in taking. As we talk about several issues in this discussion group, please focus on the OrthoEvra ad that you have in front of you.

QUESTIONS FOR DISCUSSION

Q1. What do you think about the prescription drug ads you've seen on television or in magazines?

Q2. As you look at the OrthoEvra ad, what are your initial thoughts on the ad? What do you feel when you look at this ad?

Q3. Now let's concentrate specifically on the information about benefits of the drug conveyed in this ad. Overall, what are your opinions about the benefit information?

Probe: Is it complete, accurate, readable, understandable, informative, and believable

Q4. Overall, what do you think about the information conveyed in this ad about the risks and side-effects of the drug?

Probe: Is it complete, accurate, readable, understandable, informative, and believable

Q5. When you read the ad, did you notice the page of technical information which is located on the reverse side of the OrthoEvra ad? This page is also called "brief summary". If you noticed the brief summary, did you pay attention to it? Did you read this information carefully?

Probe: Why or why not? Which specific parts of the brief summary did you or did you not read?

Q6. What do you feel when you look at this page?

Probe: Overwhelmed? Informed? Educated? Fearful?

Q7. Have you come across this kind of a brief summary before? If so, have you ever read this information? Has this information been useful to you?

Probe: In what way have you used this information?

Q8. Let's focus on the brief summary for a moment. What are your thoughts about the information in the brief summary?

Probe: Is it complete, accurate, readable, understandable, informative, and believable

Q9. In your opinion, is the brief summary necessary? Why or why not? If not, how would you convey this information to consumers like you? How will this information be useful to consumers like you?

Q10. Let's assume for a minute that our goal today is to redesign the brief summary in the OrthoEvra ad. What changes would you make to the brief summary? Which changes do you think are the most important?

Probe: Font size, color, complexity of information, layout, borders, symbols.

If Font size is mentioned, probe further on minimum font size. Show examples.

If less information mentioned, ask what information will you cut out or leave in

What is the incidence level beyond which level you would like to know which side-effects occur? E.g. 3%, 5%, 10%

Show some examples of alternative formats of brief summaries for other prescription drugs e.g. Q&A, bulleted list, risk information window, RX facts panel

Q11. If we were to create a window or a box of information on this page (lets call it the "risk information window"), what information would you like to see in this box/window?

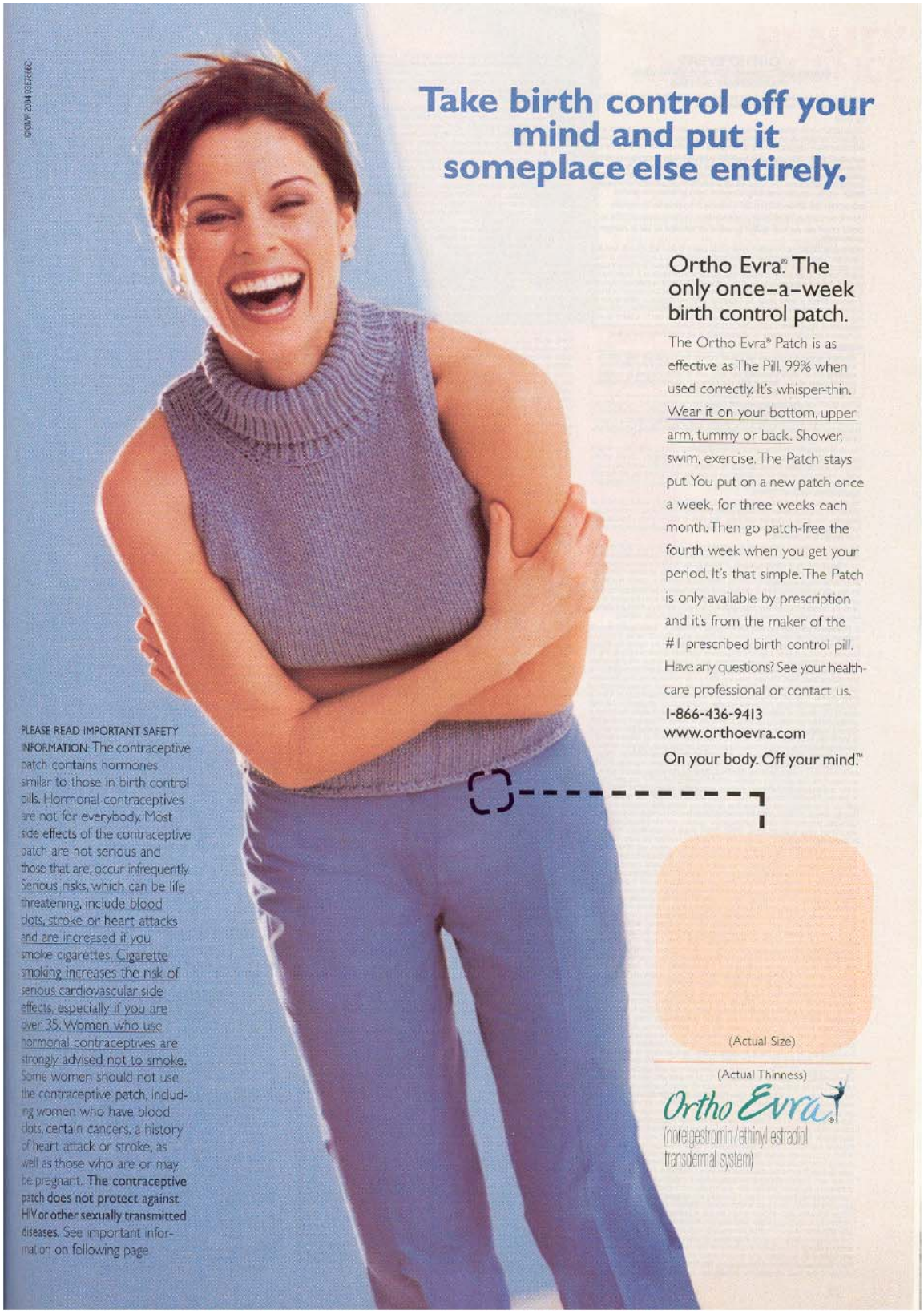
Probe: Show a format with a blank risk information window as an example

Q12. If the information in the brief summary were to be redesigned to make it more friendly to consumers like you, would you pay more attention to it?

Probe: Why or Why not?

What would make you pay more attention?

Appendix I. DTC Ad Stimuli



IMPORTANT SAFETY INFORMATION

Cigarette smoking increases the risk of serious cardiovascular side effects. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women using ORTHO EVRA should not smoke

99% effective if used as directed.
DOES NOT protect against HIV infection (AIDS) and other sexually transmitted diseases and is not indicated for use in emergency contraception.
DO NOT USE if pregnant or nursing

CAUTION: Should be used with precaution if
1) Body Weight ≥198 lbs
2) High cholesterol
3) Family history of breast cancer
4) History of depression
5) Contact lens wearers
6) Conditions worsened by fluid retention e.g. high blood pressure

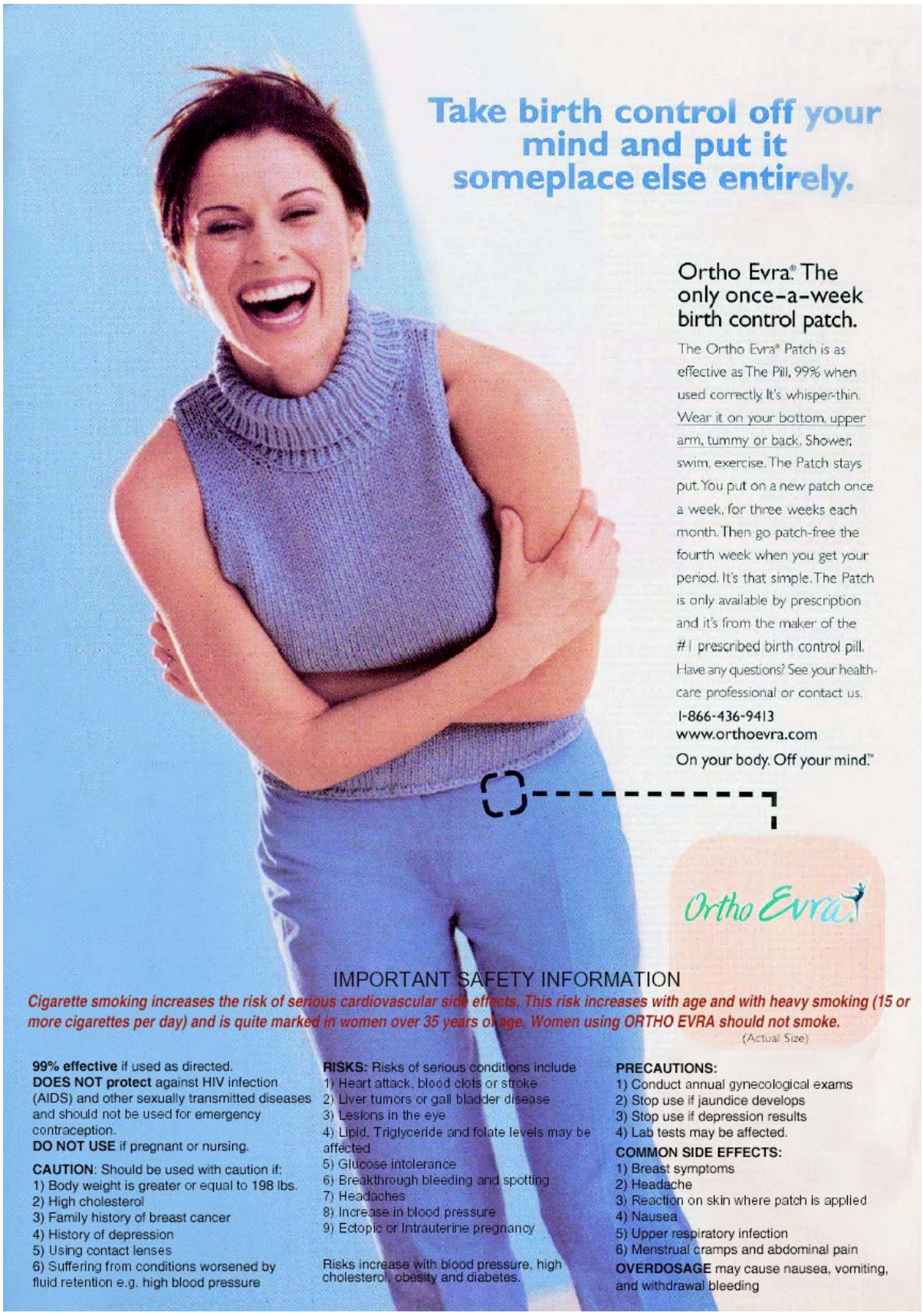
RISKS: Risks of serious conditions include
1) Heart attacks, blood clots or stroke
2) Hepatic neoplasia or gallbladder disease
3) Ocular lesions
4) Lipid, triglyceride and folate levels may be affected
5) Glucose intolerance
6) Breakthrough bleeding and spotting
7) Headaches
8) Increase in blood pressure
9) Ectopic or Intrauterine pregnancy

Risks increase with blood pressure, high cholesterol, obesity and diabetes.

PRECAUTIONS:
1) Conduct Annual Exams
2) Stop use if jaundice develops
3) Stop use if depression results
4) Lab tests may be affected

COMMON SIDE EFEECTS:
1) Breast symptoms
2) Headache
3) Application site reaction
4) Nausea
5) Upper respiratory infection
6) Menstrual cramps and abdominal pain

OVERDOSAGE may cause nausea, vomiting, and withdrawal bleeding


Take birth control off your mind and put it someplace else entirely.
Ortho Evra® The only once-a-week birth control patch.
The Ortho Evra® Patch is as effective as The Pill, 99% when used correctly. It's whisper-thin. Wear it on your bottom, upper arm, tummy or back. Shower, swim, exercise. The Patch stays put. You put on a new patch once a week, for three weeks each month. Then go patch-free the fourth week when you get your period. It's that simple. The Patch is only available by prescription and it's from the maker of the #1 prescribed birth control pill. Have any questions? See your health-care professional or contact us.
1-866-436-9413
www.orthoevra.com
On your body. Off your mind.™
Ortho Evra®
(Actual Size)
IMPORTANT SAFETY INFORMATION
Cigarette smoking increases the risk of serious cardiovascular side effects. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women using ORTHO EVRA should not smoke.
99% effective if used as directed.
DOES NOT protect against HIV infection (AIDS) and other sexually transmitted diseases and should not be used for emergency contraception.
DO NOT USE if pregnant or nursing.
CAUTION: Should be used with caution if:
1) Body weight is greater or equal to 198 lbs.
2) High cholesterol
3) Family history of breast cancer
4) History of depression
5) Using contact lenses
6) Suffering from conditions worsened by fluid retention e.g. high blood pressure
RISKS: Risks of serious conditions include
1) Heart attack, blood clots or stroke
2) Liver tumors or gall bladder disease
3) Lesions in the eye
4) Lipid, Triglyceride and folate levels may be affected
5) Glucose intolerance
6) Breakthrough bleeding and spotting
7) Headaches
8) Increase in blood pressure
9) Ectopic or Intrauterine pregnancy
Risks increase with blood pressure, high cholesterol, obesity and diabetes.
PRECAUTIONS:
1) Conduct annual gynecological exams
2) Stop use if jaundice develops
3) Stop use if depression results
4) Lab tests may be affected.
COMMON SIDE EFFECTS:
1) Breast symptoms
2) Headache
3) Reaction on skin where patch is applied
4) Nausea
5) Upper respiratory infection
6) Menstrual cramps and abdominal pain
OVERDOSAGE may cause nausea, vomiting, and withdrawal bleeding

ORTHO EVRA®

(NORELGESTROMIN / ETHINYL ESTRADIOL TRANSDERMAL SYSTEM)

ORTHO EVRA® is a combination transdermal contraceptive patch available only with a prescription.

INDICATIONS AND USAGE

- ORTHO EVRA® is indicated for preventing pregnancy. ORTHO EVRA® is 99% effective if used as directed. Safety and efficacy with ORTHO EVRA® is the same as that with oral contraceptives.
- ORTHO EVRA® does not protect against HIV infection (AIDS) and other sexually transmitted diseases. It is not indicated for use in emergency contraception.

WARNINGS

- ***Cigarette smoking increases the risk of serious cardiovascular side effects from hormonal contraceptive use.***
- ***This risk increases with age and with heavy smoking (15 or more cigarettes per day)***
- ***The risk is quite marked in women over 35 years of age.***
- ***Women who use ORTHO EVRA® should not smoke.***

RISKS

- ORTHO EVRA® is associated with an increased risk of the following
  - Heart attack, blood clots or stroke
  - Liver tumors or gallbladder disease
  - Lesions in the eye
  - Lipid, triglyceride and folate levels may be affected
  - Glucose intolerance
  - Breakthrough bleeding and spotting
  - Headaches
  - Increase in blood pressure
  - Ectopic or Intrauterine pregnancy
- The risk of serious morbidity or mortality is very small in healthy women but increases significantly with high blood pressure, high cholesterol, obesity and diabetes.

PRECAUTIONS

- **Patch Adhesion:**
  - Experience with more than 70,000 ORTHO EVRA® patches showed that 4.7% of patches were replaced because they either fell off or were partly detached.
  - Under conditions of physical exertion and changes in temperature and humidity, less than 2% of patches were replaced for detachment.
  - A patch should not be re-applied if it no longer sticks, if it has become stuck to itself or another surface, or if it has become loose or fallen off before.
  - Supplemental adhesives or wraps should not be used to hold the ORTHO EVRA® patch in place.
  - If a patch is partially or completely detached for more than one day OR if the woman is unsure how long the patch has been detached, she should start a new cycle immediately by applying a new patch.
  - Back-up contraception, such as condoms must be used for the first week of the new cycle.
- **Contraindications:** Women with the following conditions should be prescribed ORTHO EVRA® with caution and closely monitored
  - Body Weight greater than or equal to 198 lbs
  - High cholesterol
  - Family history of breast cancer or who have breast nodules
  - History of depression
  - Using contact lenses
  - Conditions worsened by fluid retention e.g. high blood pressure
- **Nursing Mothers:**
  - The effects of ORTHO EVRA® in nursing mothers have not been evaluated and are unknown.
  - Small amounts of combination hormonal contraceptive steroids have been identified in the milk of nursing mothers and a few adverse effects on the child have been reported, including jaundice, breast enlargement and interference with breast feeding by decreasing the quantity and quality of breast milk.
  - The nursing mother should be advised not to use ORTHO EVRA® until she has completely stopped breast feeding.
- **Pediatric Use:**
  - Safety and efficacy of ORTHO EVRA® is expected to be the same for post-pubertal adolescents under 16 years and older.
- **Pregnancy:**
  - Extensive studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy.
  - Studies do not indicate any heart abnormalities and limb defects, when oral contraceptives are taken mistakenly during early pregnancy.
  - ORTHO EVRA® should not be used to induce withdrawal bleeding as a test for pregnancy or to treat threatened or habitual abortion.
  - Hormonal contraceptive use should be discontinued if pregnancy is confirmed.
- **Annual Gynecological Exams:**
  - Women on ORTHO EVRA® should have annual physical examination with special reference to blood pressure, breasts, abdomen and pelvic organs, including cervical cytology, and relevant laboratory tests.
- **Jaundice:**
  - If jaundice develops, ORTHO EVRA® use should be stopped
- **Depression:**
  - Women who become significantly depressed while using ORTHO EVRA™ should stop using ORTHO EVRA®
- **Laboratory Tests:**
  - Certain endocrine and liver function tests and blood components may be affected by hormonal contraceptives
- **Drug Interactions:**
  - ORTHO EVRA® may interact or have reduced effectiveness with some antibiotics, antifungals, anticonvulsants (e.g. barbiturates, griseofulvin, rifampin, phenytoin, ampicillin, phenylbutazone, carbamazepine, felbamate, oxycarbazepine, topiramate, tetracycline), anti-HIV protease inhibitors, St. John's wort, atorvastatin, ascorbic acid, acetaminophen, itraconazole, ketoconazole, cyclosporins, prednisolone, theophylline, temazepam, salicylic acid, morphine and clofibric acid.

ADVERSE REACTIONS

- The most common adverse events reported by 9% to 22% of women were the following, in order of decreasing frequency:
  - Breast symptoms
  - Headache
  - Reaction on skin where patch is applied
  - Nausea
  - Upper respiratory infection
  - Menstrual cramps and abdominal pain
- The most frequent events leading to discontinuation in 1% to 2.4% of women included
  - Nausea and/or vomiting
  - Reaction on skin where patch is applied
  - Breast symptoms
  - Headache
  - Emotional lability
- Other adverse events associated with all combination hormonal contraceptives are
  - Blood clots
  - Heart attack
  - High blood pressure
  - Gall bladder disease or liver tumors
- There is evidence of an association between ORTHO EVRA® use and blockage of blood supply.

OVERDOSAGE

- Overdosage may cause nausea, vomiting, and withdrawal bleeding
- In case of suspected overdose, all ORTHO EVRA® patches should be removed and symptoms should be treated.

ADDITIONAL INFORMATION

- For more information visit www.orthoevra.com, call 1-866-436-9413 or see your health-care professional.

ORTHO-McNEIL

ORTHO-McNEIL PHARMACEUTICAL, INC
Raritan, New Jersey 08869

ISSUED NOVEMBER 2001 631-10-660-1B

ORTHO EVRA®

(NORELGESTROMIN / ETHINYL ESTRADIOL TRANSDERMAL SYSTEM)

WHAT IS ORTHO EVRA®?

ORTHO EVRA® is a combination transdermal contraceptive patch available only with a prescription.

HOW EFFECTIVE IS ORTHO EVRA®?

ORTHO EVRA® is 99% effective if used as directed. Safety and efficacy with ORTHO EVRA® patch is the same as that with oral contraceptives.

WHAT IS ORTHO EVRA® INDICATED FOR?

ORTHO EVRA® is indicated for preventing pregnancy.

WHAT IS ORTHO EVRA® NOT INDICATED FOR?

ORTHO EVRA® does not protect against HIV infection (AIDS) and other sexually transmitted diseases and is not indicated for use in emergency contraception.

WHAT DO I NEED TO KNOW BEFORE TAKING ORTHO EVRA® ?

Warnings - Cigarette smoking increases the risk of serious cardiovascular side effects from hormonal contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use ORTHO EVRA® should not smoke.

WHAT ARE THE RISKS ASSOCIATED WITH ORTHO EVRA®?

Use of combination hormonal contraceptives may increase risks of serious conditions such as:

1) Heart attacks, blood clots or stroke
2) Liver tumors or gallbladder disease
3) Lesions in the eye
4) Lipid, triglyceride and folate levels may be affected
5) Glucose intolerance
6) Breakthrough bleeding and spotting
7) Headaches
8) Increase in blood pressure
9) Ectopic/Intrauterine pregnancy

The risk of serious morbidity or mortality is very small in healthy women but increases significantly with high blood pressure, high cholesterol, obesity and diabetes.

WILL THE ORTHO EVRA® PATCH STICK TO THE SKIN?

Experience with more than 70,000 ORTHO EVRA® patches showed that 4.7% of patches were replaced because they either fell off or were partly detached. Under conditions of physical exertion and changes in temperature and humidity, less than 2% of patches were replaced for detachment.

WHAT IF THE PATCH DOES NOT STICK OR COMES OFF?

A patch should not be re-applied if it no longer sticks, if it has become stuck to itself or another surface, or if it has become loose or fallen off before. Supplemental adhesives or wraps should not be used to hold the ORTHO EVRA® patch in place. If a patch is partially or completely detached for more than one day OR if the woman is unsure how long the patch has been detached, she should start a new cycle immediately by applying a new patch. Back-up contraception, such as condoms must be used for the first week of the new cycle.

WHO SHOULD BE PRESCRIBED ORTHO EVRA® WITH CAUTION?

Women with the following conditions should be prescribed ORTHO EVRA® with caution and closely monitored

1) Body Weight greater than or equal to 198 lbs
2) High cholesterol
3) Family history of breast cancer or who have breast nodules
4) History of depression
5) Using contact lenses
6) Conditions worsened by fluid retention e.g. high blood pressure

CAN ORTHO EVRA® BE USED IN NURSING MOTHERS?

The effects of ORTHO EVRA® in nursing mothers have not been evaluated and are unknown. Small amounts of combination hormonal contraceptive steroids have been identified in the milk of nursing mothers and a few adverse effects on the child have been reported, including jaundice, breast enlargement and interference with breast feeding by decreasing the quantity and quality of breast milk. The nursing mother should not use ORTHO EVRA® until she has completely stopped breast feeding.

CAN ORTHO EVRA® BE USED IN ADOLESCENTS UNDER 16 YEARS?

Safety and efficacy of ORTHO EVRA™ is expected to be the same for post-pubertal adolescents under 16 years and older.

IS ORTHO EVRA® USE SAFE BEFORE PREGNANCY?

Extensive studies have revealed no increased risk of birth defects in women who have used oral contraceptives prior to pregnancy. Studies do not indicate any heart abnormalities and limb defects, when oral contraceptives are taken unknowingly during early pregnancy.
ORTHO EVRA® should not be used to induce withdrawal bleeding as a test for pregnancy or to treat threatened or habitual abortion. Hormonal contraceptive use should be discontinued if pregnancy is confirmed.

WHAT PRECAUTIONS SHOULD BE TAKEN WITH ORTHO EVRA®?

1) ANNUAL GYNECOLOGICAL EXAMS - Women on ORTHO EVRA® should have annual physical examination with special reference to blood pressure, breasts, abdomen and pelvic organs, including cervical cytology, and relevant laboratory tests.
2) JAUNDICE - If jaundice develops, ORTHO EVRA® use should be stopped.
3) DEPRESSION - Women who become significantly depressed while using ORTHO EVRA® should stop using ORTHO EVRA®
4) LABORATORY TESTS - Certain endocrine and liver function tests and blood components may be affected by hormonal contraceptives

DOES ORTHO EVRA® INTERACT WITH OTHER DRUGS?

ORTHO EVRA® may possibly interact or have reduced effectiveness with some antibiotics, antifungals, anticonvulsants (e.g. barbiturates, griseofulvin, rifampin, phenytoin, ampicillin, phenylbutazone, carbamazepine, felbamate, oxycarbazepine, topiramate, tetracycline), anti-HIV protease inhibitors, St. John's wort, atorvastatin, ascorbic acid, acetaminophen, itraconazole, ketoconazole, cyclosporins, prednisolone, theophylline, temazepam, salicylic acid, morphine and clofibric acid.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF ORTHO EVRA®?

The most common adverse events reported by 9% to 22% of women were the following, in order of decreasing frequency:

1) Breast symptoms
2) Headache
3) Reaction on the skin where patch is applied
4) Nausea
5) Upper respiratory infection
6) Menstrual cramps and abdominal pain

The most frequent events leading to discontinuation in 1% to 2.4% of women included nausea and/or vomiting, reaction on skin where patch is applied, breast symptoms, headache and emotional lability

Other adverse events associated with all combination hormonal contraceptives are 1) Blood clots 2) Heart attack 3) High blood pressure 4) Gallbladder disease or liver tumors.

There is evidence of an association between ORTHO EVRA® use and blockage of blood supply.

WHAT ARE THE SYMPTOMS OF OVERDOSAGE?

Overdosage may cause nausea, vomiting, and withdrawal bleeding. In case of suspected overdose, all ORTHO EVRA® patches should be removed and symptoms should be treated.

WHAT SHOULD I DO IF I HAVE ADDITIONAL QUESTIONS?

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ORTHO EVRA®

RX DRUG FACTS

ACTIVE INGREDIENTS: ***Norelgestromin*** **(6 mg) and** ***Ethinyl Estradiol*** **(0.75 mg)**

EFFECTIVENESS:
- **99% effective** if used as directed.

USES:
- **Used to prevent pregnancy**
- **DOES NOT protect** against HIV infection (AIDS) and other sexually transmitted diseases and should not be used for emergency contraception.
- **DO NOT USE** if pregnant or nursing

CAUTION: Use with caution if
1) Body Weight greater than or equal to 198 lbs
2) High cholesterol
3) Family history of breast cancer
4) History of depression
5) Using contact lenses
6) Suffer from conditions worsened by fluid retention e.g. high blood pressure

COMMON SIDE EFFECTS:
1) Breast symptoms
2) Headache
3) Reaction on skin where patch is applied
4) Nausea
5) Upper respiratory tract infection
6) Menstrual cramps and abdominal pain

RISKS: Risks of serious conditions include
1) Heart attack, blood clots or stroke
2) Liver tumors or gallbladder disease
3) Lesions in the eye
4) Lipid, triglyceride and folate levels may be affected
5) Glucose intolerance
6) Breakthrough bleeding and spotting
7) Headaches
8) Increase in blood pressure
9) Ectopic or Intrauterine pregnancy

Risks increase with blood pressure, high cholesterol, obesity and diabetes.

WARNINGS:
Cigarette smoking increases the risk of serious cardiovascular side effects. Risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women using ORTHO EVRA should not smoke.

PRECAUTIONS:
1) Conduct annual gynecological exams
2) Stop use if jaundice develops
3) Stop use if depression results
4) Lab tests may be affected

OVERDOSAGE:
Overdosage may cause nausea, vomiting, and withdrawal bleeding.

FOR MORE INFORMATION:
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