INFORMATION TO USERS

This manuscript has been reproduced from the microfilm master. UMI films the text directly from the original or copy submitted. Thus, some thesis and dissertation copies are in typewriter face, while others may be from any type of computer printer.

The quality of this reproduction is dependent upon the quality of the copy submitted. Broken or indistinct print, colored or poor quality illustrations and photographs, print bleedthrough, substandard margins, and improper alignment can adversely affect reproduction.

In the unlikely event that the author did not send UMI a complete manuscript and there are missing pages, these will be noted. Also, if unauthorized copyright material had to be removed, a note will indicate the deletion.

Oversize materials (e.g., maps, drawings, charts) are reproduced by sectioning the original, beginning at the upper left-hand corner and continuing from left to right in equal sections with small overlaps. Each original is also photographed in one exposure and is included in reduced form at the back of the book.

Photographs included in the original manuscript have been reproduced xerographically in this copy. Higher quality 6" x 9" black and white photographic prints are available for any photographs or illustrations appearing in this copy for an additional charge. Contact UMI directly to order.
A confirmatory analysis of the antecedent of perceived behavioral control and the theory of planned behavior: An examination of physicians’ reporting intentions

Funk Orsini, Paula Ann, Ph.D.

The Ohio State University, 1992
A CONFIRMATORY ANALYSIS OF THE
ANTECEDENT OF PERCEIVED BEHAVIORAL CONTROL
AND THE THEORY OF PLANNED BEHAVIOR:
AN EXAMINATION OF PHYSICIANS' REPORTING INTENTIONS

DISSertation

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

By

Paula A. Funk Orsini, B.S., M.S.

The Ohio State University
1992

Dissertation Committee:
Dev S. Pathak, D.B.A.
Robert E. Burnkrant, Ph.D.
John J. Kennedy, Ph.D.

Approved by
College of Pharmacy
To my husband, Michael
ACKNOWLEDGEMENTS

I am deeply indebted to my adviser and mentor, Dr. Dev S. Pathak, who has guided me throughout my doctoral studies and this dissertation project. I also thank my minor adviser, Dr. Robert E. Burnkrant, for his significant contribution to my graduate training and dissertation. In addition, I am grateful to Dr. John J. Kennedy and Dr. Robert C. MacCallum, for their substantial impact on my research training.

I offer my thanks to the many physicians who participated in this research project. In addition, I am grateful to Dr. Patricia Temple, who supported me in my attempt to recruit physicians' participation in the investigation.

I extend my deepest appreciation to Ms. Melinda Bertl, Ms. Ming Fisher, and Mr. Michael Orsini, who assisted with the data collection and computer entry. In addition, I thank Mr. Stephen Skarupa, Dr. Stuart Speedie, and Ms. Lenore Brashler, who helped with the data analysis and final document preparation.

I offer special thanks to my family and friends, who have loyally supported me throughout the many years of graduate training. Lastly, I am especially grateful to my husband, Michael, whose love and support helped make my doctoral studies and the completion of this dissertation possible.
VITA

May 16, 1956
Born: Marietta, Ohio

June, 1979
B.S. Pharmacy: The Ohio State University, Columbus, Ohio

June, 1980
One year residency accredited by the American Society of Hospital Pharmacists: The Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania

1980-1984
Staff Pharmacist, The Ohio State University, Columbus, Ohio

1985-1986
Graduate Teaching Associate, College of Pharmacy, The Ohio State University, Columbus, Ohio

1987-1989
Graduate Teaching Associate, College of Pharmacy, The Ohio State University, Columbus, Ohio

August, 1991-present
Assistant Professor in Pharmacy Practice and Administrative Sciences, School of Pharmacy, University of Maryland at Baltimore, Baltimore, Maryland

FIELDS OF STUDY

Major Field Pharmacy

Studies in Pharmaceutical Administration
Consumer Behavior
TABLE OF CONTENTS

DEDICATION .................................................................................................................................ii

ACKNOWLEDGEMENTS ...........................................................................................................iii

VITA ...............................................................................................................................................iv

LIST OF TABLES .........................................................................................................................vii

LIST OF FIGURES ........................................................................................................................x

CHAPTER PAGE

I. INTRODUCTION TO THE STUDY ......................................................................................... 1
   Nature of the Problem ............................................................................................................. 3
   Surveillance of Adverse Drug Events .................................................................................... 4
   Understanding Physicians' Reporting Behaviors ......................................................... 10
   Behavioral Intention Models ............................................................................................ 10
   A Model of Physicians' Reporting Intentions .............................................................. 15
   Statement of the Problem ................................................................................................. 17
   Significance of the Study ................................................................................................. 19
   Limitations and Delimitations ......................................................................................... 23
   Definition of Terms .......................................................................................................... 25
   Organization of the Study ................................................................................................. 26

II. REVIEW OF LITERATURE ...............................................................................................28
   The Theory of Reasoned Action ...................................................................................... 28
   TRA: Components and Causal Structure ...................................................................... 30
   TRA: Validity and Reliability Issues ............................................................................. 36
   TRA: Applications and Research Concerns ................................................................. 42
III. RESEARCH DESIGN AND PROCEDURE ........................................189

Exploratory Research .................................................................189
  Purpose of Exploratory Research ...........................................189
  Methodology of Exploratory Research ......................................190
  Results of Exploratory Research ...........................................193

Sampling Procedure ...............................................................197
  Target Population and Sample Selection .................................197
  Sample Size Determination ..................................................198

Data Collection ..............................................................................200
  Development of the Data Collection Instrument .......................200
  Item Sequence and Physical Characteristics ............................201
  Pretest ....................................................................................202
  Questionnaire Administration ................................................203
  Follow-Up ................................................................................204

Definition and Measurement of Variables ....................................204
  Types of Variables in Covariance Structural Models ..................205
  The Model of Physicians' Reporting Intentions: Variables ...........206
  Definition and Measurement of Other Variables ........................224

Evaluation of the Questionnaire ...............................................225
  Content Validity ......................................................................225
  Predictive Validity ...................................................................226
  Construct Validity ....................................................................226

Sources of Error and Bias .............................................................231
  Frame Errors .........................................................................231
  Sampling Errors ......................................................................233
  Nonresponse Errors .............................................................234
  Measurement Errors .............................................................235

Data Analysis ...............................................................................238
  Questionnaire Response .......................................................238
  Analytical Techniques for Research Hypotheses ........................239
IV. RESULTS AND DISCUSSION .................................................................273

Characteristics of the Study Data ..........................................................273
Results of Submodel Analyses ...............................................................275
  RQ 1: Structure of Expectancy-Value Attitude .............................275
  RQ 2: Structure of the NBMC Composite .................................280
  RQ 3: Antecedent of Perceived Behavioral Control ..................281
  RQ 4: Structure of PBC's Antecedent ...........................................284
Summary of Submodel Analyses ..................................................285
Results of Overall Model Analysis ..................................................287
  Measurement Properties of Observed Variables ..................288
  Evaluation and Comparison of Nested Models ...................294
Results of Research Hypotheses ...................................................305
Results of the Specification Search .............................................306
  Specification Search: Step 1 ..................................................307
  Specification Search: Step 2 ..................................................309
Further Respecification Considerations ..................................313
Summary of Model Results .....................................................316

V. CONCLUSIONS AND RECOMMENDATIONS ...........................................319

Summary: Spontaneous Reporting Intentions ............................319
Conclusions ...................................................................................321
Limitations and Generalizability of Study ..................................325
Recommendations for Future Research Endeavors ......................329

APPENDICES

A. Exploratory Study: Data Collection Instrument ..................331
B. Primary Investigation: Data Collection Instrument ...............337
C. OSUHP Medical Director: Support Memos .........................350
D. Second Wave Cover Letter ....................................................352
E. Input Correlation Matrices: CBSI and CB Models ..................354

LIST OF REFERENCES .................................................................365
# LIST OF TABLES

<table>
<thead>
<tr>
<th>TABLE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. TPB: Ajzen's Measures of Perceived Behavioral Control</td>
<td>77</td>
</tr>
<tr>
<td>2. TPB: Other Measures of Perceived Behavioral Control</td>
<td>78</td>
</tr>
<tr>
<td>3. TPB: Findings of Empirical Studies by Ajzen and Colleagues</td>
<td>102</td>
</tr>
<tr>
<td>4. TPB: Findings of Other Empirical Studies</td>
<td>113</td>
</tr>
<tr>
<td>5. TPB Versus TRA: Predictive Ability</td>
<td>116</td>
</tr>
<tr>
<td>6. Salient Belief-Evaluations, Referents, and Control Factors</td>
<td>196</td>
</tr>
<tr>
<td>7. Summary of LISREL Terminology</td>
<td>207</td>
</tr>
<tr>
<td>8. Submodels: Nested Comparisons</td>
<td>276</td>
</tr>
<tr>
<td>9. Submodels: Chi-Square Difference Tests</td>
<td>277</td>
</tr>
<tr>
<td>10. Expectancy-Value Two-Dimensional Submodel: Structural Parameter Estimates</td>
<td>279</td>
</tr>
<tr>
<td>12. Control Belief-Strength of Influence Two-Dimensional Submodel: Structural Parameter Estimates</td>
<td>286</td>
</tr>
</tbody>
</table>
15. Nested Model Comparisons: Structural Parameter Estimates (Directional) .................................................................290
17. Nested Models: Fit Comparisons and Chi-Square Difference Tests ...............................................................................298
19. Measurement Properties of Respecified Indicators and their Constructs ........................................................................310
20. Input Correlation Matrix: Control Belief Model ..................................355
21. Input Correlation Matrix: CBSI Model .................................................360
# LIST OF FIGURES

<table>
<thead>
<tr>
<th>FIGURE</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Overall Model of Physicians' Spontaneous Reporting Intentions</td>
</tr>
<tr>
<td>2.</td>
<td>The Theory of Reasoned Action</td>
</tr>
<tr>
<td>3.</td>
<td>The Theory of Planned Behavior</td>
</tr>
<tr>
<td>4.</td>
<td>Dimensionality of EV Composite</td>
</tr>
<tr>
<td>5.</td>
<td>Dimensionality of NBMC Composite</td>
</tr>
<tr>
<td>6.</td>
<td>Antecedent of Perceived Behavioral Control</td>
</tr>
<tr>
<td>7.</td>
<td>Dimensionality of CBSI Composite</td>
</tr>
<tr>
<td>8.</td>
<td>Dimensionality of CB Construct</td>
</tr>
<tr>
<td>9.</td>
<td>Models for Research Question 5</td>
</tr>
<tr>
<td>10.</td>
<td>Models for Research Question 6</td>
</tr>
<tr>
<td>11.</td>
<td>Models for Research Question 7, Hypothesis 7.1</td>
</tr>
<tr>
<td>12.</td>
<td>Models for Research Question 7, Hypotheses 7.2 and 7.3</td>
</tr>
<tr>
<td>13.</td>
<td>Overall Model of Physicians' Spontaneous Reporting Intentions</td>
</tr>
<tr>
<td>14.</td>
<td>Overall Structural and Measurement Models Proposed for Physicians' Reporting Intentions</td>
</tr>
<tr>
<td>15.</td>
<td>Models for Research Questions 5 to 7</td>
</tr>
</tbody>
</table>
16. Overall Structural and Measurement Model with Standardized Parameter Estimates: Resultant Model ..........................318
CHAPTER 1
INTRODUCTION TO THE STUDY

The skyrocketing nature of health care expenditures has been a formidable issue in the United States for many years. National health care costs were $12 billion in 1950, $69.1 billion in 1970, and reached $666.2 billion in 1990 (Gibson and Mueller, 1977; Letsch et. al., 1988; NDMA, 1991). An equal, if not greater, concern has been the increasing proportion of the U.S. gross national product (GNP) attributed to these expenditures. For example, health care costs accounted for 4.5% of the GNP in 1950, 7.2% in 1970, 12.2% in 1990, and have been projected to reach $1.5 trillion, or 15% of the nation’s GNP by the year 2000 (HCFA, 1987; NDMA, 1991).

One issue, in particular, that has generated considerable concern is the nation’s growing aged population and their use of health care resources. In 1987, people age 65 or older comprised 12% of the total U.S. population and consumed 36% of all personal health care, up from 30% in 1977 (Waldo et. al., 1989). It has been estimated that this group will continue to increase, comprising 21% of the total population by the year 2030. Waldo et. al. (1989) have reported that the aged currently spend four times per capita for health care as the rest of the population. Obviously, the impact of this expanding segment on the nation’s total health care bill is expected to significantly increase.
Over the past decade, numerous cost-containment efforts have been implemented, generating a wide spectrum of health care delivery and finance alternatives. These efforts, however, have yet to reverse or even contain the rate of escalating costs. Therefore, researchers, health care providers, and policy makers, must persistently and carefully study factors that contribute to the utilization of health care services. These efforts can guide the development of policies targeted at controlling the misuse of health care resources and ultimately, national health care expenditures.

This dissertation addresses one of the many factors contributing to the use of health care services: adverse drug events. Specifically, this research examines physicians' intentions to report serious adverse drug events to the Food and Drug Administration (i.e. FDA) within the theoretical framework of a behavioral intention model, the Theory of Planned Behavior (Ajzen, 1985; Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1987; Ajzen, 1988; Beck and Ajzen, 1991).

This chapter consists of several sections. The first two sections briefly discuss the nature of the problem regarding adverse drug events and the approach taken in this investigation to understand physicians' intent to report them. The third section states the research problem examined in this investigation. The fourth section discusses the significance of conducting the research. The next three sections address the assumptions, the limitations and delimitations, and the definition of terms with respect to this investigation. Finally, the organization of the dissertation's remaining four chapters is presented.
Nature of the Problem

Adverse drug events (ADEs) are associated with morbidity, mortality, and increased utilization of health care services. ADEs are estimated to be the primary source of or strongly influence hospitalization in 3% to 22% of admitted patients (Hurwitz, 1969b; Miller, 1974; Caranasos et. al., 1974; Bergmann and Wiholm, 1981; Davidsen et. al., 1988). Faich et. al. (1987a) found that of the 26,381 ADE reports submitted to the FDA in 1986, 21% mentioned hospitalization or its prolongation.

It has also been reported that adverse drug events occur in 3% to 28% of patients in the hospital who are receiving drug therapy (Hurwitz and Wade, 1969; Smidt and McQueen, 1972; Miller, 1973; Mitchell et. al., 1979). As many as 50% to 80% of these ADEs were classified as moderately severe or severe, and 3.2% resulted in death. In the study conducted by Caranasos et. al. (1974), 6% of patients experiencing an adverse event expired. More recently, death was reported as an outcome in 4.1% (n=33,192) of the domestic ADE reports submitted to the FDA in 1987 (Kennedy et. al., 1989).

Studies suggest that elderly patients are more apt to experience adverse drug events than younger patients for several reasons (Hurwitz, 1969a; Smidt and McQueen, 1972; Miller, 1973; Vestal, 1978; Cadieux, 1989; Col, 1990). First, elderly patients generally have multiple disease states and take more medications than younger patients. Second, many of the disease states in the elderly require continuous and lifelong drug therapy. Third, some of the diseases which are more prevalent in the elderly (e.g. congestive heart failure) require medications associated with greater potential toxicities. Furthermore, pharmacokinetic differences (e.g. drug absorption, metabolism, and elimination) seen with increased age apparently
increase the elderly patient's sensitivity to the toxic effects of some drugs. Finally, generally speaking, the elderly patient is more apt to be noncompliant with the medication regimen, thus leading to inappropriate drug use. The need to prevent, monitor and treat adverse drug events in this population, therefore, is essential.

**Surveillance of Adverse Drug Events**

In the past, the primary source of recognizing a drug's previously unknown adverse effects has been the serendipitous discovery by health practitioners using the drug in their patients. For example, a spontaneous report by a practicing pediatrician was responsible for uncovering the risk associated with using benzyl alcohol-preserved solutions in neonates (Soffer, 1985). More recently, the Flank Pain Syndrome (FPS) associated with using the nonsteroidal anti-inflammatory suprofen was detected by spontaneous reporting (Rossi et. al., 1988). Most noteworthy about the suprofen experience is that neither the drug's European and U.S. clinical trials nor the three years postmarketing use in Europe prior to U.S. market approval provided any evidence of this adverse event.

Spontaneous reporting (SR) can occur via: (1) anecdotal reports in the professional literature, and (2) voluntary verbal or written reports by health care practitioners to interested parties, such as the FDA, the sponsoring pharmaceutical manufacturer, or special registries for surveillance of adverse drug events. The Spontaneous Reporting System (SRS) that is maintained by the FDA's Division of Epidemiology and Surveillance is the largest spontaneous reporting system within the United States.

The primary objective of the SRS is to collect previously unrecognized and serious adverse drug events, especially for newly marketed drugs. Due to the large
number of reports received, the FDA encourages SRS participants to focus on serious events that: (1) cause new or prolong current hospitalizations, (2) suggest an increased frequency in a previously known serious event, (3) are associated with congenital anomalies, (4) cause cancer, or (5) result in death (Rogers, 1987). Currently, the ones of greatest concern are those not contained in the drug's official labeling, i.e. package insert, which are serious or life-threatening (FDA, 1990).

The FDA's reporting system has demonstrated its value in detecting new adverse drug events and in contributing economically to the post-marketing efforts of the United States. Specifically, a spontaneous report can generate a signal that stimulates: (1) further investigation of the drug, (2) a change in the drug product's official labeling, or (3) the drug's removal from the market.

In spite of the FDA's proven contribution, researchers recognize the defect inherent to this type of surveillance system, particularly within this country. Although the United States was one of the first countries to begin collecting reports, it has had one of the lowest reporting rates when compared to several European countries. Griffin (1986) surveyed fifteen countries and found that when the average rate of reporting was based on population, Denmark and New Zealand ranked first and second, respectively. The U.S. ranked ninth and had only 25% of the reporting rate of Denmark. When the average reporting rate was based on the number of practicing physicians, Denmark's rate still tripled the rate of the United States. Although some of the differences in reporting rates may be attributed to variations between the nations with respect to prescribing habits, susceptibility to experiencing adverse drug events, monitoring biases, and data interpretation (e.g. report sources included in a nation's data base), the gap between Denmark and the United States remains significant.
Rogers et. al. (1988) recently examined the awareness and use of the FDA's surveillance system by 3000 physicians randomly selected from a major metropolitan area. Responses from 1121 physicians (response rate=37%) provided alarming information regarding the awareness of the SRS by physicians, the major population of contributing reporters. First, a fairly high proportion of physicians (37%) reported detecting an adverse drug event in one of their patients during the year of interest. However, a mere 5% of these events were directly reported to the FDA. Furthermore, only 18% of the adverse events were reported to any surveillance system. More disturbingly, a moderately high percentage (43%) of physicians reported being unaware of the existence of the SRS. Although the design and response rate of Rogers et. al. study limit generalizing its results, their findings lend support to the extent of under-reporting in the United States that has been found by Griffin (1986).

Researchers have examined the reporting behaviors of physicians in an effort to identify factors that influence their decisions to report or to not report. Several factors have been identified, including characteristics of the physician, the adverse drug event, the drug product, and the reporting process, itself. (Koch-Weser et. al., 1969; Milstien et. al., 1986; Griffin, 1984; Juergens, 1990). In short, research has indicated that physicians are more likely to report an adverse drug event that: (1) is serious rather than minor, (2) has never or minimally been documented, i.e. unlabeled or unexpected, rather than labeled or expected, and (3) is associated with a newer drug rather than a drug with longer market exposure. How and the extent to which these factors influence the physician's decision to report or to not report the adverse drug event, however, have not been addressed.
The study cited previously by Rogers et. al. (1988) attempted to also measure the "attitudes" of physicians toward the FDA's surveillance system and the reporting of adverse drug events, in general. The survey instrument included nine belief statements in which physicians were requested to report the extent to which they agreed with each statement on a four-point scale ranging from strongly agree (1) to strongly disagree (4). The results from this study indicated that physicians believe that their reporting is their professional obligation (mean=1.5); would not lead to their filling out endless forms (mean=2.6); might substantially contribute to medical knowledge (mean=3.5); would not increase their personal liability (mean=3.1); would be more likely to occur if there were an easier method to report (mean=1.9); should not be financially reimbursed (mean=3.3); and does not take too much time (mean=2.8).

Rogers et. al. (1988) also found differences in beliefs between physicians who had previously reported to the FDA and physicians who had not previously reported. Specifically, significant differences between "reporters" and "nonreporters" were found with respect to three beliefs: (1) reporters more strongly agreed that it was their professional obligation to report to the FDA than nonreporters (p<.001), (2) although both groups generally disagreed that reporting an adverse drug event would increase their personal liability, more nonreporters held this belief than reporters (p=.005), and (3) even though the majority of both groups believed that the current reporting system is inconvenient, nonreporters agreed more strongly than reporters that they would more likely report if it were more convenient (p=.002). Generally speaking, then, physicians seemed to hold relatively positive beliefs with respect to their role in reporting adverse drug events to the FDA. However, some of the beliefs of physicians who had previously reported to the FDA were more positive
than the beliefs of physicians who had not previously reported. Therefore, it appears that physicians' beliefs about their reporting an adverse drug event to the FDA are indicative of their reporting behavior.

The study by Rogers et. al. (1988) included a logistic regression in which 15% of the variance in the probability of physician reporting was explained by five factors, including: (1) the unavailability of the FDA's adverse drug event form, (2) the ADE was a minor or an expected side effect, (3) the event was previously documented, (4) the physician's proportion of inpatient practice, and (5) the physician's medical specialty. These results supported previous research finding that serious and unlabeled adverse events, rather than minor and labeled ones, are more likely to reported. In spite of its previously described limitations, the large amount of unexplained variance in this study's regression model suggests that factors influencing physicians' reporting have yet to be identified and measured.

In conclusion, research has demonstrated that adverse drug events substantially impact morbidity and mortality by influencing hospital admissions, increasing the length of hospital stays, and precipitating deaths. It is suspected that, for several reasons, the statistics reported to date conservatively reflect the current and future impact of adverse drug events on morbidity and mortality. First, these indices have been derived from hospital and inpatient data settings, thus excluding ambulatory and extended-care environments. Second, controversy over what constitutes an adverse drug event, how it should be classified (e.g. seriousness), and when it should be reported is rampant in the medical literature. Thus, it is likely that many adverse events are neither recognized nor reported. Third, the future promises an expanding elderly population that is predisposed to experiencing adverse drug
events. Therefore, the incidence of adverse drug events and their impact on the utilization of future health care resources warrant concern.

Systems for surveilling adverse drug events are present in the United States as well as many other countries. The FDA maintains a spontaneous reporting system that has demonstrated its value and economic contribution to this nation's postmarketing efforts. Research has demonstrated, however, that the rate of voluntary reporting in this country is significantly less than the rates attained in several European countries. A recent investigation suggests that a large portion of practicing physicians, the largest contributors to the data base of reports, may be unaware of the FDA's spontaneous reporting system. This is particularly alarming because the FDA has been actively recruiting the submission of reports from physicians as well as other health care professionals.

The adverse drug events of greatest concern to the FDA are serious and previously unrecognized, or unexpected, events because they present the greatest threat to the use of health care resources. Previous efforts to identify the factors that influence physicians' reporting behavior have yielded relatively limited information. That is, although some factors have been identified as associated with the decision to report or to not report, an understanding of how, why, and to what extent these factors impact the reporting decision is not known. This type of information can be obtained, however, by examining physicians' reporting behavior within a theoretical framework.
Understanding Physicians' Reporting Behaviors

Understanding and predicting physicians' reporting of serious adverse drug events can be assisted with a theoretical framework designed to examine this behavior. Numerous theoretical models, the majority of which are rooted in psychology, have been developed to understand and predict human behavior. One of the most dominant group of models originating in the marketing literature but applied in many research settings is the multi-attribute or expectancy-value attitude models. This group of models specifies a causal relationship flowing from cognitive structure to attitude, thus providing diagnostic utility. The behavioral intention models have been the most widely used and studied multi-attribute models.

Behavioral Intention Models

The model used in this investigation for understanding physicians' spontaneous reporting behavior is based upon the behavioral intention models. A behavioral intention model was preferred for two primary reasons. First, a substantial number of studies have successfully applied this type of model. Second, reporting behaviors of physicians could not be practically measured by either direct observations or self-report methods in this investigation because: (1) reports of adverse drug events submitted to the FDA are kept confidential, and (2) serious adverse drug events occur infrequently in some physicians' practices and thus, obtaining a self-report measure at any specified time may either not allow enough time for one to occur or allow too much time for a successful follow-up. Therefore, a behavioral intention model, which views an individual's behavioral intention (BI) as the immediate determinant of his behavior, seemed the optimal choice.
Fishbein's Behavioral Intention Model, introduced in 1967, has been refined over the years, becoming known as the Theory of Reasoned Action (Fishbein, 1967a, 1967b, 1967c; Fishbein and Ajzen, 1975; Ajzen and Fishbein, 1980). This model views an individual's behavioral intention (BI) to perform or to not perform a given behavior as the immediate determinant of his behavior (B). The individual's intention is determined by two empirically weighted factors, one representing his attitude toward performing the given behavior (ATT) and the other representing his subjective norm (GSN) or perception of the social pressures placed on him to perform the behavior. Each of these constructs is determined by a composite in which: (1) salient behavioral beliefs are multiplied by their corresponding evaluations to generate expectancy-value attitude (EV), the antecedent of ATT; and (2) salient normative beliefs are multiplied by their motivation to comply counterparts to generate the normative belief-motivation to comply (NBMC) composite, the antecedent of GSN.

The Theory of Reasoned Action (TRA) has been a popular model used in all areas of research. Its popularity has been based on its parsimonious nature, ease of use, and predictive utility. In addition, considerable research assessing the validity of the model as a whole, as well as its components and their measures, has been conducted. However, critical evaluation of the theory as a causal model of human behavior has led to many issues of debate, in particular, the model's restriction to predicting behaviors under volitional control. Although Ajzen and Fishbein (1980, p.5) claimed that "most actions of social relevance are under volitional control", critics of the Theory of Reasoned Action argued the error in this assumption, thus spurring an alteration to the model by Ajzen.

1 GSN represents the latent subjective norm variable to distinguish it from the measured SN variable.
The introduction of 'perceived behavioral control' as the third determinant of behavioral intention transforms the TRA into the Theory of Planned Behavior (TPB). The concept of 'perceived behavioral control' has been defined as an individual's belief about how easy or difficult performance of the behavior is expected to be and is assumed to reflect past experience as well as anticipated obstacles or impediments (Ajzen, 1985; Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1987; Ajzen, 1988; Beck and Ajzen, 1991). The concept's inclusion in the model addresses some of the criticisms launched against the Theory of Reasoned Action in that the newer model is useful in predicting many behaviors that are either volitional or involitional in nature. In short, the Theory of Planned Behavior, unlike the Theory of Reasoned Action, recognizes that regardless of the strength of a given behavioral intention, its successful execution is dependent on the individual's actual control over performing the behavior.

Since the introduction of the Theory of Planned Behavior, Ajzen and his colleagues have consistently maintained that a set of beliefs about the availability of requisite resources and opportunities provide the basis for, or underlie, an individual's perception of control over a given behavior (Ajzen, 1985; Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1987). This set of beliefs, referred to as 'control beliefs', are defined as beliefs about factors, both internal and external to the individual, that influence the individual's perception of control over performing the behavior. Further literature published to date has yet to extend the conceptualization of the PBC construct beyond this set of 'control beliefs'.

Another conceptual issue pertaining to the PBC construct is the extent to which an individual's perception of control over a given behavior reflects his past performance of the behavior. This issue has been raised because prior experience
with the behavior is likely to provide the individual information about the internal and external factors that would impact his performance of the behavior, thus suggesting that past behavior and perceived behavioral control conceptually overlap.

According to the Theory of Planned Behavior, perceived behavioral control has both motivational and nonmotivational implications for intentions and behavior. In terms of its motivational effects, if the individual believes that he lacks the factors, such as resources, opportunities, etc., requisite to perform a given behavior, he is unlikely to form a strong intention to engage in the behavior even if his attitude and subjective norm with respect to the behavior are favorable. In terms of nonmotivational effects, the degree of success to which a behavior can be predicted is dependent on the factors that will directly impair or facilitate an individual's actual control over behavioral performance, regardless of the individual's intention. To the extent that an individual intends to perform the behavior and has adequate control, he will succeed in performing the behavior. If the individual's perception of control does not accurately reflect his actual control, the measure of perceived behavioral control adds minimally to the prediction of behavior. That is, if the individual's perception of control is not accurate, the motivational effect of perceived behavioral control on behavioral intention can occur but the nonmotivational effect of perceived control on behavior is not observed.

The Theory of Planned Behavior, then, proposes that perceived behavioral control can directly influence the formation of an individual's intention, thus indirectly impacting behavior, i.e. PBC---\(\rightarrow\) BI. Perceived behavioral control can also directly impact behavior, i.e. PBC---\(\rightarrow\) B, if the individual's perception of the factors requisite for performing the behavior is accurate. If the behavior is completely volitional in nature, the concept of perceived behavioral control is
irrelevant in the prediction of the behavior and the Theory of Planned Behavior reduces to the Theory of Reasoned Action.

A relatively limited number of studies have tested the Theory of Planned Behavior. Generally speaking, these studies have provided mixed support for the model. Some have found support for the PBC---＞BI pathway, less have found support for the PBC---＞B pathway, and a few have found no support for the model. One that included a measure of past behavior for three behaviors under study found it to be a significant predictor of behavioral intentions, above and beyond any effect from perceived behavioral control.

This investigation proposes that several factors may contribute to the findings generated from the studies of the Theory of Planned Behavior. First, the theory's overall causal structure, as defined by Ajzen and his colleagues, does not include multidimensional representations for the EV and NBMC constructs even though a two-dimensional structure has received support for both constructs in studies with the Theory of Reasoned Action. Second, the current conceptualization of the perceived behavioral control construct does not specifically address the determinant or antecedent of the construct, rather 'control beliefs' are defined as underlying, or the basis for, the construct. Third, operationalization of the perceived behavioral control construct has generated relatively inadequate measures, in terms of reliability and validity. Finally, the majority of research has been conducted with regression analysis, which estimates path coefficients without addressing the attenuation due to unreliable measures.
A Model of Physicians' Reporting Intentions

Previous research has indicated that physicians may perceive some lack of control over reporting to the FDA, i.e. availability of time, forms, etc. Therefore, the Theory of Planned Behavior is the behavioral intention model of choice for studying physicians' reporting intentions. The literature reviewing the Theory of Planned Behavior identified several issues that may have contributed to the model's lack of support in previous research. These issues are addressed by seven sets of research questions posed in this investigation, including:

1. What is the structure, or underlying dimensional nature, of EV within the TPB? Does this study's results support previous research with the TRA finding that the antecedent of ATT is better represented with a two-dimensional rather than a unidimensional structure?

2. What is the structure, or underlying dimensional nature, of the NBMC construct within the TPB? Does this study's results support previous research with the TRA finding that the antecedent of GSN is better represented as a two-dimensional rather than a unidimensional structure?

3. What is the antecedent of PBC? Does an antecedent consisting of a composite of control beliefs and the strength of their influence (CBSI) over an individual's performance of the behavior provide a better representation of the PBC construct than the set of 'control beliefs' (CB) proposed by Ajzen and his colleagues?

4. What is the structure, or underlying dimensional nature, of the antecedent of PBC? Does research support a two-dimensional representation of the antecedent of PBC such as that found with EV and the NBMC composites within the TRA?

5. Does PBC have an impact on BI when added to the TRA, i.e. is the TPB a more adequate model for predicting physicians' reporting intentions than the TRA?

6. What are the determinants of past behavior (PB)? Does PB have an independent effect on BI or ATT within the TPB? To what extent does PB overlap with the PBC construct?
7. Do physicians' attitudes toward the FDA, i.e. attitude toward an object (ATT₀), have any effect on BI that is independent of ATT, GSN, and PBC with respect to the act of reporting serious adverse drug events to the FDA?

The hypotheses proposed to test these research questions are fully developed in the 'Study Rationale' section at the end of Chapter II. Briefly summarized, this investigation proposes that the expectancy-value composite is better represented as a two-dimensional rather than a unidimensional structure. One dimension is proposed to represent the positive consequences of reporting a serious adverse drug event to the FDA and the other represents the negative consequences. The normative belief-motivation to comply composite is proposed to exist similarly in that one dimension represents referents viewed by physicians to be 'authoritative' in nature and the other dimension represents 'nonauthoritative' referents.

In addressing the next three research questions, this investigation proposes that the antecedent of perceived behavioral control is a composite (CBSI) consisting of salient 'control beliefs' multiplied by their respective 'strength of influence'. This composite is compared to the set of 'control beliefs' proposed by Ajzen and his colleagues to underlie perceived behavioral control. This study also proposes that the structure underlying the antecedent of perceived behavioral control is two-dimensional rather than unidimensional. One dimension is proposed to represent factors that are internal to the physician that can influence his control over reporting the adverse drug event; the second dimension is proposed to represent factors that are external to the physician. In addition, this investigation proposes that physicians' perception of control over reporting serious adverse drug events is a significant predictor of their intentions to report. Finally, this investigation proposes that physicians' past reporting behavior and their attitude toward the FDA have a
direct influence on their intentions to report, i.e. an effect that is not mediated by
the model's other components.

The overall model that is proposed in this investigation to explain and predict
physicians' spontaneous reporting intentions is illustrated in Figure 1. The
application of this model should lead to a greater understanding of the determinants
of physicians' reporting of adverse drug events and suggest methods for improving
the reporting rate. In addition, the model's application should result in further
evaluation of both the Theory of Planned Behavior as a causal model for explaining
and predicting human behavior, and the role of each construct within the model.

Statement of the Problem

A brief review of the trends in the health care industry shows that health care
expenditures continue to rise and account for an increasing proportion of our
nation's gross national product. Adverse drug events, particularly serious and
unlabeled, or unexpected ones, contribute to these costs via increased morbidity,
mortality, and subsequent use of health care services. The growth of our aged
population, combined with its members' predisposition toward experiencing adverse
drug events, implies that the use of health care resources will continue to increase,
thus further impacting the nation's total health care budget.

Efforts to identify why physicians decide to report or to not report adverse drug
events to the FDA have identified a relatively small number of factors that account
for the probability of physicians' reporting. Therefore, much is yet to be learned
about the factors underlying physicians' reporting behaviors, in terms of how and to
what extent they influence physicians' reporting of adverse drug events.
Figure 1: Overall Model of Physicians' Spontaneous Reporting Intentions

*For diagrammatic simplicity, the proposed correlations between ATT, GSN, PBC, PB, and ATT₀ are omitted.
Many of the questions pertaining to physicians' reporting of adverse drug events are answerable within the theoretical framework of the Theory of Planned Behavior. However, much is yet to be addressed regarding this theory, including: (1) the model's overall causal structure; (2) the conceptualization and operationalization of its components, particularly the concept of perceived behavioral control; (3) issues relating to the model's validity and reliability as well as the development of valid measures for the model's components; and (4) the adequacy of the model as compared to its predecessor, the Theory of Reasoned Action.

In summary, the problem posed in this investigation is, in fact, two-fold. First, an understanding of the factors underlying physicians' reporting of adverse drug events is needed. Second, issues pertaining to the Theory of Planned Behavior have yet to be addressed. The research undertaken in this dissertation is an effort to gain the insight necessary both to influence physicians' reporting behavior and to contribute to the theoretical development of the Theory of Planned Behavior.

Significance of the Study

This study is significant for both theoretical and pragmatic reasons. First, this investigation attempts to significantly contribute to the conceptual development of the Theory of Planned Behavior. The 'perceived behavioral control' concept has not been theoretically developed to the extent where its antecedent as well as the determinants and structure underlying this antecedent are known. The lack of conceptual development with respect to the perceived behavioral control construct leaves a relatively large gap in understanding the overall causal structure of the Theory of Planned Behavior. Answers to the research questions developed from this
investigation's conceptual process may help to narrow this gap, thus providing further support of the viability of both perceived behavioral control as a construct in the model and the overall causal structure of the Theory of Planned Behavior.

Second, extending the conceptualization of perceived behavioral control should provide guidance for developing appropriate methods to operationalize the construct. Success with this step will assist in developing valid and reliable measures of perceived behavioral control. This investigation expects that these efforts will add further support of both the construct's role in the Theory of Planned Behavior and the overall model's adequacy in explaining and predicting human behaviors under varying degrees of involitional control.

Third, data analysis via covariance structural equation modeling should provide clearer evidence of the validity and reliability with respect to the measurement and the structural components, or models, of the Theory of Planned Behavior over previous research using regression analyses. In particular, the choice of this multivariate technique will significantly contribute to understanding the structure underlying the antecedents of behavioral intention's determinants. This investigation's data analysis estimates path coefficients while considering the attenuation resulting from unreliable measures, thus providing a 'truer' picture of the relationships among the model's components.

Fourth, the role of past behavior on components in behavioral intention models has remained largely unanswered. This investigation attempts to clarify whether past behavior directly and/or indirectly impacts physicians' intention to report serious ADEs to the FDA. In addition, this study should answer whether or not past behavior directly impacts attitude or if its effects are mediated indirectly via the determinants of expectancy-value attitude. Furthermore, this study may
substantially contribute to the understanding of conceptual and measurement overlap between past behavior and perceived behavioral control. Although past behavior has not specifically been proposed as a determinant of perceived behavioral control, this study may significantly advance the understanding of both the 'perceived behavioral control' and the 'past behavior' concepts. Again, increasing the information available about this potential overlap may help narrow the gap in understanding the Theory of Planned Behavior as a causal model for explaining and predicting human behavior.

In terms of pragmatic purposes, this investigation is also significant for several reasons. First, a greater understanding of the factors impacting physicians' intention to report serious adverse drug events to the FDA is critical for developing mechanisms to influence their reporting behavior. Past research has identified characteristics of the practitioner, the adverse event, the drug, and the reporting process, itself, which influence physicians' reporting behaviors. However, a greater understanding of the factors underlying physicians' reporting behavior can be gained from examining: (1) physicians' beliefs about the consequences of reporting to the FDA and how they evaluate these consequences, (2) the individuals or groups who might have expectations about whether physicians should or should not report and the extent to which physicians want to comply with these individuals or groups, (3) physicians' beliefs about factors that can influence their control over reporting serious adverse drug events to the FDA and the extent to which these factors impair or facilitate their control, (4) the extent to which physicians' past behavior influences their intent to report adverse events, and (5) whether or not physicians' attitudes toward the FDA affect their intentions to report to the FDA, independent of their attitude toward the act of reporting. Thus, a model built upon the framework
provided by the Theory of Planned Behavior can increase our understanding of the factors underlying physicians' reporting behavior.

By increasing our understanding of the factors underlying physicians' intention to report, in terms of how and to what extent they influence their decision to report, strategies aimed to positively influence reporting behavior can be proposed. For example, if this research indicates that physicians' attitudes toward reporting a serious adverse drug event to the FDA influence their intentions to report to a greater extent than their perceptions of behavioral control or subjective norms, efforts to improve physicians' reporting behavior may best succeed if they are directed at positively impacting physicians' beliefs with respect to the reporting process. Also, if this study finds that physicians perceive a lack of control over reporting to the FDA and this perception significantly and negatively impacts their intention to report, strategies can be developed by the FDA to improve physicians' perceptions of and/or actual control over their reporting behavior. In short, the results of this investigation may suggest that physicians' reporting behavior can be influenced in various ways, i.e. by introducing one or more intervention. Potential interventions include influencing physicians' beliefs about: reporting serious adverse drug events to the FDA, the individuals or groups that might have expectations about their reporting behavior, and the factors perceived to influence their control over reporting to the FDA. Other methods worth examining to improve physicians' reporting behavior may be suggested by comparing the extent to which physicians' attitudes, subjective norms, perceived behavioral control, and past behavior influence their intentions to report.

Finally, a better understanding of the factors underlying physicians' reporting behaviors can benefit the FDA in their attempt to increase spontaneous reporting of
serious adverse drug events. In addition, other systems relying on spontaneous reports, such as manufacturers, specialized reporting registries, in-hospital drug surveillance systems, etc., may gain some insight to the factors leading to physicians' participation in ADE reporting. Therefore, this research may provide pragmatic value to parties involved with voluntary surveillance systems as well as provide a basis for further research in this area.

Limitations and Delimitations

This investigation explored spontaneous reporting intentions of only one type of health care provider, namely physicians. Physicians were selected for study because past research indicated that they contribute the most reports to the FDA's surveillance data bank via their submissions to the manufacturer and their direct reports to the FDA. In addition, efforts to increase physicians' reporting activities have been a primary focus of the FDA, professional health care organizations, and individual health care providers.

This study examined physicians' reporting intentions for only serious adverse drug events. Exploratory research indicated that minor adverse events occurred frequently and were so insignificant in nature that examining physicians' intention to report them would be inconsequential. This finding, coupled with the FDA's current focus on serious adverse drug events, supported this investigation's approach. Within the proposed theoretical framework, this study identified the factors determining physicians' reporting behavior as well as the relationships among and the structure underlying these factors.
This research also addressed several issues pertaining to behavioral intention models. For example, the conceptualization of the Theory of Planned Behavior's 'perceived behavioral control' construct was further developed in an effort to identify its antecedent and its underlying structure. In addition, this study attempted to both further assess the role of past behavior in the proposed theoretical model and to evaluate current measures of past behavior. These goals encompassed a more general goal of the investigation: to identify the multi-attribute model explaining the most variance in physicians' intentions to report serious adverse drug events to the FDA.

Major limitations of this research lay with the use of a mail survey for data collection. First, since participation in the study was voluntary, selection bias may have resulted in data not sufficiently representing the target population. Other forms of nonresponse bias (e.g. incomplete or inappropriately completed questionnaires) may also limit this study's results. Efforts to guard against these limitations and their potential impact on the study's results are discussed in Chapters III and V.

Other limitations of this investigation concern the physicians' reporting model as proposed. First, the model does not include the behavior component as specified in behavioral intention models because its inclusion would have necessitated waiting sufficient time for physicians to encounter a relatively infrequent event (i.e. a serious adverse event) in their practice. Consequently, a measure of physicians' behavior would significantly increase the length, costs, etc. of this investigation. Therefore, this study limited its focus to physicians' intention to report. Further analysis of the impact of perceived behavioral control, past behavior, and behavioral intention on physicians' reporting activities would require follow-up study.
Lastly, the generalization of this study's results is limited. Specifically, since this research only examines physicians' intention to report serious adverse drug events to the FDA, it is inappropriate to generalize study results to: (1) other health care provider categories or target populations, (2) adverse drug events that are not serious, and (3) physicians' reporting of serious adverse drug events to parties other than the FDA.

Definition of Terms

A number of terms pertaining to health care are used in this investigation. Since the study focuses on the FDA's spontaneous reporting system, those pertaining to the SRS concur with definitions provided by the FDA for marketed drugs (FDA, 1989). A number of other terms pertaining to components in this investigation's model are also used. However, these terms are best defined when the behavioral intention models are discussed and the physician reporting model proposed in this investigation is developed in Chapter II.

Adverse Drug Event (ADE): Commonly referred to in the literature as adverse drug experience, adverse drug reaction (ADR), adverse reaction, and drug-induced illness. The terms "adverse drug event" and "adverse drug experience" are currently preferred because they are less likely to imply that a drug is the cause of the event. For the purposes of this study, an adverse drug event is defined as "any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug
overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any significant failure of expected pharmacologic action" (FDA, 1989).

**Serious Adverse Drug Event (ADE):** Refers to "an adverse drug experience that is fatal or life-threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly, cancer or overdose" (FDA, 1989).

**Unexpected (Unlabeled) ADE:** An ADE that "is not listed in the current labeling for the drug product and includes an event that may be symptomatically and pathophysiologically related to an event listed in the labeling, but differs from the event because of greater severity or specificity" (FDA, 1989).

**Organization of the Study**

The remainder of this dissertation consists of four chapters. Chapter II focuses on literature reviewing behavioral intention models. In addition, this chapter addresses the study rationale and the development of the theoretical model used to examine physicians' reporting intentions. Finally, the research questions and the hypotheses developed to answer these questions are provided.

Chapter III describes the purpose, procedure, and results of the exploratory research. In addition, it addresses the methodology and design of this investigation. This chapter also discusses the development of the data collection instrument as well as its evaluation. In addition, possible sources of error and bias in this investigation are addressed. Lastly, Chapter III includes the data analysis. This section discusses
the application and interpretation of LISREL VII, followed by a brief presentation of the specific data analysis techniques chosen to test each research hypothesis.

Chapter IV addresses the results of the investigation. This section includes results pertaining to characteristics of the data and the measures used to collect it. In addition, the results obtained from testing the research hypotheses developed in the second chapter are presented and discussed. Finally, this chapter discusses the study's modeling process, in terms of the resultant model that provided the most plausible representation of this study's data.

Lastly, Chapter V summarizes the investigation and draws conclusions from the study's results. This chapter also addresses both limitations of the study and provides recommendations for future research endeavors.
CHAPTER II
REVIEW OF LITERATURE

The literature reviewed in this chapter pertains to behavioral intention models as initially proposed and developed by Fishbein, Ajzen, and their colleagues. The chapter consists of three major sections. The first section discusses several issues related to the Theory of Reasoned Action. This discussion is necessary because it provides the foundation for understanding the second section: the Theory of Planned Behavior. Since the Theory of Planned Behavior is the focus of this research, its discussion is in much greater depth than its predecessor. The final section addresses the study rationale. Specifically, this section develops the model, the research questions, and the specific hypotheses used in this investigation to examine the target behavior: physicians' reporting of serious adverse drug events (ADEs) to the FDA.

The Theory of Reasoned Action

Since the late 1960's, Fishbein's model for the prediction of behavioral intentions, commonly referred to as Fishbein's Behavioral Intention Model and most recently as the Theory of Reasoned Action (Fishbein and Ajzen, 1975; Ajzen and Fishbein, 1980), has been one of the most widely recognized yet critically scrutinized multi-attribute attitude models in the psychological and marketing
In predicting and understanding human behavior, the theory views an individual's intention to perform or to not perform a given behavior as the immediate determinant of that behavior.

The Theory of Reasoned Action (TRA) is based on several assumptions. First, it assumes that an individual is a rational actor who systematically gathers and evaluates information in forming a behavioral intention. Second, the theory assumes that a small set of constructs can predict behavioral intention and subsequent behavior. That is, the influence of all variables, both internal and external to the individual, has no direct effect on behavior but indirectly influences behavior via the components in the model's theoretical framework. Lastly, the theory assumes that the studied behavior is under the individual's volitional control and involve a choice (e.g. between reporting or not reporting the adverse drug event to the FDA).

The following discussion of the Theory of Reasoned Action is divided into four sections. The first section addresses the model's components and causal structure as defined by Fishbein, Ajzen, and their colleagues (Fishbein and Ajzen, 1975; Ajzen and Fishbein, 1977; Ajzen and Fishbein, 1980; Ajzen, 1985; Ajzen, 1986; Ajzen and Madden, 1986; Ajzen, 1987; Ajzen, 1988). Secondly, the TRA's validity and reliability in terms of previous validation research and unidimensionality issues are addressed. The third section reviews literature that has applied the TRA and the limitations found with the model. Finally, some concluding remarks pertaining to the Theory of Reasoned Action are presented.
The following description of the components and causal structure of the Theory of Reasoned Action primarily reflects the theoretical framework prescribed by Fishbein, Ajzen and their colleagues. The Theory of Reasoned Action consists of four major components: behavior (B), behavioral intention (BI), attitude toward the behavior (ATT), and subjective norm (SN). This section first discusses behavioral intentions and their relationship with behavior. Next, general background information is provided regarding the model's components and overall causal structure. Finally, the antecedents of attitude and subjective norm, namely expectancy value attitude (EV) and the normative belief-motivation to comply (NBMC) composite are examined.

**Intentions, Behavior, and BI-B Relationship**

According to the TRA, intentions are behavioral dispositions that presumably capture all factors motivating an individual to perform or to not perform a given behavior. Ajzen (1987) defines an intention as an indication of the extent to which an individual will try or the effort he is willing to exert in order to perform the behavior. An intention remains a behavioral disposition until opportunity allows the intention to translate into action. Thus, under certain circumstances, an individual's behavior at a given point in time is determined by or highly correlated with his intention or motivation to perform the specified behavior at the specified time. In short, behavioral intentions are the immediate antecedents of actions or behaviors.

According to Fishbein and Ajzen (1975), three factors influence the magnitude of the behavior-behavioral intention (B-BI) relationship: (1) the degree to which the intention and behavior correspond in their levels of specificity, (2) the stability of
the intention, and (3) the extent to which carrying out the intention is under the individual's control. Each of these factors is briefly discussed below.

In terms of the degree to which the intention and behavior correspond in their levels of specificity, four elements contribute to the level of specificity for measures of both behavior and behavioral intention: action, target, context, and time. Ajzen and Fishbein (1977) found in reviewing empirical research addressing the attitude-behavior relationship, that stronger relationships existed when high levels of correspondence between at least the target and action elements were obtained. These authors maintain that strong relationships between intention (predictor) and behavior (criterion) are obtained when both variables are measured at the same level of specificity (Fishbein and Ajzen, 1975). High correspondence between attitude (predictor) and behavioral intention (criterion) as well as between subjective norm (predictor) and intention also leads to strong relationships. An example of high correspondence between these two predictors of behavioral intention and the criterion (intention) for the behavior under study in this investigation is to include physicians' reporting (action) of serious adverse drug events (context) to the FDA (target) in the future (time) in the measures of attitude, subjective norm, and behavioral intention.

In terms of the intention's stability, once an individual has formed an intention to perform a given behavior, factors can influence the formed intention before he executes the behavior. These factors may include changes in variables that determine the individual's attitude toward the behavior and/or subjective norm. Thus, an alteration in an individual's original behavioral intent can interrupt the behavior's completion.
Finally, the volitional nature of a given behavior largely determines the strength of the B-BI relationship. For example, a person may be unable to carry out an intention if: (1) he or she does not have the required skills, abilities, resources, or cooperation of others, (2) the behavior's execution is dependent on other people or events, or (3) the behavior can only occur after a sequence of other behaviors are completed (Ajzen, 1985; Ajzen, 1986; Ajzen and Madden, 1986; Ajzen 1988).

Fishbein and Ajzen acknowledge that predicting behavior from an intention may sometimes be less than accurate and is more accurate at the aggregate than at the individual level. However, they provide recommendations for measuring variables that they claim will minimize the attenuation of the behavior-behavioral intention relationship.

**Overall Model Structure: Background**

According to the Theory of Reasoned Action, an individual's behavioral intention (BI) is determined by two factors: (1) the individual's attitude toward performing the given behavior (ATT), and (2) the individual's subjective norm (SN) or perception of the social pressures placed on him to perform the behavior (Fishbein and Ajzen, 1975). The individual's behavioral intention, then, is a function of attitude and subjective norm, each empirically weighted as shown in Equation 2.1.

\[
B - BI = (ATT)w_1 + (SN)w_2
\]

(Eq. 2.1)
Obviously, the greater the value for one or both composites (i.e. ABW₁ and/or SNW₂), the greater the behavioral intention. According to Fishbein and Ajzen, determining the weights greatly enhances the model's explanatory power.

In general, a person's attitude toward performing a given behavior is predicted by his or her beliefs. These beliefs may be formed as a result of an individual's direct observation or learning, indirect learning processes such as accepting information from friends or media, inference processes that lead to self-generated beliefs, etc. (Ajzen and Fishbein, 1975; Ajzen, 1988). For example, if a physician believes that reporting a serious ADE will result in favorable outcomes, his attitude toward reporting will also be favorable. Conversely, if the physician believes that reporting the ADE will lead to unfavorable outcomes, his attitude toward reporting will be unfavorable.

The antecedent of attitude is specified as an expectancy-value (EV) composite, consisting of two elements: (1) the person's expectancy or beliefs (bᵢ) that performing the behavior leads to 'n' number of consequences, and (2) the person's evaluation (eᵢ) of each of these 'n' consequences (Ajzen and Fishbein, 1975; Ajzen, 1988). This belief-evaluation composite underlying attitude, henceforth referred to as expectancy-value attitude, is represented in Equation 2.2.

\[
EV = \sum_{i=1}^{n} b_i e_i
\]

(Eq. 2.2)
Interpersonal differences in attitude toward the behavior are attributed to differences in: (1) belief strength, i.e. the perceived likelihood that performing a given behavior is associated with an outcome(s) in question, and (2) the evaluation of an outcome (Fishbein and Ajzen, 1975).

It should be noted that while an individual may hold a great number of beliefs about a given behavior, it appears that he can attend to only a relatively small number, such as five to nine, at one time (Ajzen and Fishbein, 1980; Ajzen, 1985). It is these 'salient' beliefs that are the determinants of the individual's attitude.

A similar composite underlies an individual's subjective norm, consisting of: (1) the individual's normative belief (NBj), i.e. the belief that a particular referent thinks that the individual should or should not perform the behavior, and (2) the individual's motivation to comply (MCj) with the referent. All salient referents, including individuals and/or groups of individuals, contribute to this composite. The subjective norm composite is expressed in Equation 2.3.

\[
SN = \sum_{j=1} MB_j MC_j
\]

(Eq. 2.3)

The TRA is a model, then, which attempts to explain and predict human behavior by linking personal and normative beliefs with behavior. Theoretically, the effects of any external variables (e.g. demographic characteristics, personality traits, and attitudes toward targets) on predicting a person's behavior are mediated indirectly via their impact on: (1) the person's attitude toward performing the
Figure 2: The Theory of Reasoned Action (Ajzen and Fishbein, 1980, p. 84)
behavior, (2) the person's subjective norm pertaining to the behavior, (3) the relative importance or weight assigned to each of these composites (See Figure 2).

**TRA: Validity and Reliability Issues**

This section consists of two parts. The first part reviews literature validating the Theory of Reasoned Action as well as recommendations by Fishbein and Ajzen for valid and reliable use of the model in predicting human behavior. The second part addresses a relatively recent concern regarding model and measurement validation, namely dimensionality. Throughout both parts, the role of confirmatory factor methods in validating models and measures is discussed.

**Validity and Reliability: General Issues**

Since the late 1970's, researchers have challenged the validity of the components and the pattern or structure of the relationships among them as proposed in the Theory of Reasoned Action model. One area that has been strongly challenged and has led to considerable research is the distinction between the TRA's attitudinal and normative components (Miniard and Cohen, 1979; Smetana and Adler, 1980; Miniard and Cohen, 1981). As one example, Miniard and Cohen (1981) declared that Fishbein and Ajzen's (1975) justification for distinguishing between the TRA's attitudinal and normative components lacked adequate conceptual basis. Since this charge, however, other research has supported these constructs' conceptual distinction.

Researchers have challenged areas other than the separation of attitudinal and normative influence including, but not limited to: (1) the predictive validity of the EV--- >ATT and NBMC--- >SN pathways, (2) the inclusion of pathways such as
ATT→B to improve the predictive validity of the overall TRA model and (3) the inclusion of other components (e.g. past behavior, resources, self-efficacy, etc.) to improve the model's ability to predict intention and behavior. Burnkrant and Page (1982; 1988) have provided a more thorough review of previous research validating the Theory of Reasoned Action. Further discussion of proposed changes in the TRA model to improve its predictive validity has been more appropriately placed in an upcoming section.

The introduction and growing use of confirmatory techniques such as structural equation analysis have provided new and significantly greater opportunities for assessing models' validity and reliability. In one such case, Burnkrant and Page (1982) used structural equation analysis to assess the predictive, convergent, and discriminant validity of the proposed determinants of behavioral intention in the TRA model. Study results supported a model in which unidimensional attitudinal and normative components were correlated but achieved discriminant and convergent validity. Also, the model's predictive validity was supported for the reported intention to donate blood.

Further support for expectancy-value attitude and the NBMC composite's validity (i.e. construct, content, and predictive validity) and reliability have been provided by researchers examining both the Theory of Reasoned Action and Ajzen's (1985; 1986; 1988; 1991) Theory of Planned Behavior. Sheppard et. al. (1988) have recently documented the TRA's predictive validity and utility in two meta-analyses. Additional validity and reliability support that has been generated from investigations of the Theory of Planned Behavior is presented later in discussing that model.
Issues of the TRA’s validity and reliability have also been recognized by Fishbein and Ajzen in that they have recommended safeguards against invalid and unreliable results obtained from measurement instruments that are designed to examine intentions and behavior (Fishbein and Ajzen, 1975; Ajzen and Fishbein, 1980; Ajzen and Madden, 1986). For example, they recommend developing the measurement instrument based on research that has previously identified salient beliefs and normative referents applicable to both the behavior and the population under investigation. This data is oftentimes obtained from exploratory or pilot studies in which subjects are asked to list: (1) advantages and disadvantages of performing the studied behavior (used to form the belief and evaluation statements), and (2) the people who might have expectations about whether or not they should perform the behavior (used to form the normative belief statements).

Ajzen and Fishbein (1980, Appendices A and B) have also provided a standardized format for developing a data collection instrument to measure the TRA’s components. The measures in their proposed questionnaire format primarily include semantic differential-type scales. In general, it has been found that the reliability of this type of scale is relatively good (Osgood et. al., 1957). Fishbein and Ajzen (1975) also report relatively high reliabilities for the single-item seven-point scales developed to measure behavioral intention as long as the scales are anchored with probabilistic bipolar adjectives, such as probable/improbable or likely/unlikely. Thus, when data collection instruments based on the Theory of Reasoned Action are developed properly, these authors maintain that reliability issues do not pose a threat to the study.

In short, research to date appears to support the predictive and construct validity of the Theory of Reasoned Action. However, other questions pertaining to the
reliability and validity of the TRA and its components have been raised. One issue ignored by Ajzen and Fishbein but not by other researchers is the dimensionality of both expectancy-value and the normative belief-motivation to comply composites.

Other Validity Issues: Dimensionality

Over the past decade, several researchers have emphasized the importance of establishing a given construct's unidimensionality before using an instrument that is designed for unidimensional measurement (Anderson and Gerbing, 1982; Hunter and Gerbing, 1982; Danes and Mann, 1984; Hattie, 1985; Gerbing and Anderson, 1988). A large percentage of the research using the behavioral intention models has ignored this validity-related issue in that the dimensionality of expectancy-value attitude and the normative belief-motivation to comply composite is not even mentioned; these constructs are simply assumed to be unidimensional (e.g. Pomazal and Jaccard, 1976; Ajzen and Fishbein, 1980; Sullivan and Joyce, 1981; Burnkrant and Page, 1982; Manstead et. al., 1983; Ajzen and Madden, 1986; Prestholdt et. al., 1987; Ajzen, 1988; McCaul et. al., 1988; Fishbein and Stasson, 1990). However, a few studies have examined, in the context of the Theory of Reasoned Action, the dimensional structure of the expectancy-value and normative belief-motivation to comply composites.

In terms of the expectancy-value composite underlying TRA's attitudinal component, Bagozzi (1981a, 1981b) has suggested that EV can be better represented as a multidimensional rather than a unidimensional construct. Although the interpretation of Bagozzi's results may be suspect due to the study's use of nontraditional measures of expectancy-value attitude, the multidimensional representation of this construct has been supported by other researchers.
Burnkrant and Page (1988) proposed a multidimensional structure of expectancy-value attitude toward the act of giving blood based, in part, on Pomazal and Jaccard's (1976) finding that both positive and negative consequences were associated with this behavior. Specifically, Burnkrant and Page proposed a two-dimensional structure for expectancy-value attitude in which one dimension represented positive consequences and the second dimension represented negative consequences. These two dimensions were theoretically supported by research in information processing that supports a network representation of memory. Research in information processing suggests that memory is a network of associations in which objects, ideas, individuals, etc. are linked together based on learning experiences. Therefore, the authors hypothesized that linkages in memory among the positive consequences and among the negative consequences are stronger than the linkages between positive and negative consequences of donating blood, thus yielding a two-factor model. A structural equation analysis of the entire TRA model with LISREL VI (Joreskog and Sorbom, 1984) indicated that the TRA model with a two-dimensional representation of EV fit the study data significantly better (p < .01) than a model with a unidimensional representation. Therefore, this study's results supported Bagozzi's (1981a; 1981b) proposed multidimensional structure of expectancy-value attitude.

The main focus of Burnkrant and Page's (1988) study of blood donation behavior, however, was on the TRA's normative component. The investigators hypothesized that the NBMC composite also existed as a multidimensional rather than a unidimensional construct for at least two reasons: (1) if expectancy-value attitude was multidimensional, it was logical to expect NBMC also to be multidimensional since the two constructs were structurally similar, and (2) NBMC's
A confirmatory factor analysis of Burnkrant and Page's (1988) NBMC 'submodel' indicated that the multidimensional (i.e. two-factor) model fit the study data significantly better than the unidimensional (i.e. one-factor) model (p < .05). In addition, the TRA model comprised of a two-dimensional NBMC and a unidimensional EV 'submodel' was compared via structural equation analysis to a TRA model comprised of unidimensional NBMC and EV 'submodels'. Results of this analysis showed that the two-factor NBMC model fit the data significantly better than the one-factor model, thus supporting a multidimensional representation of the NBMC composite (p < .01).

In a study conducted by Grube et. al. (1986), the TRA and two variant models were used to predict smoking intentions and behaviors. A principal components analysis (oblique rotation) indicated that the beliefs underlying the subjective norm loaded on four rather than one factors. Although this study's results should be viewed tentatively based on its exploratory nature, the limitations associated with a principal components analysis, and the authors' use of nontraditional subjective norm measures (only measures of normative beliefs), it provides some support for
Burnkrant and Page's (1988) findings of a multidimensional representation of the normative belief-motivation to comply composite.

In summary, research generated over the past decade has indicated that establishing a construct's dimensional structure is imperative to its valid and reliable measurement. However, the majority of researchers studying or applying the Theory of Reasoned Action, or one of its variants, have neglected to consider the dimensionality issue. Instead, both normative belief-motivation to comply and belief-expectancy products are routinely summed to generate a single NBMC and EV score, respectively. As noted by Bagozzi (1982; 1983), this sort of summation assumes that the measured constructs are unidimensional. If this assumption is violated, however, Bagozzi argues that invalid predictions of intentions and behavior can occur. Therefore, it seems prudent for a researcher to assess the dimensional nature of the constructs under study before developing measures and collecting or analyzing data.

**TRA: Applications and Research Concerns**

Numerous researchers have provided convincing support for the TRA's predictive utility in the sociology, psychology, marketing, and health care literatures (Ajzen and Fishbein, 1977; Schlegal et. al., 1977; Vinokur-Kaplan, 1978; Ajzen and Fishbein, 1980; Smetana and Adler, 1980; Montano, 1986; Godin et. al., 1989; McClenney and Neiss, 1989; Chinburapa and Larson, 1991). As previously mentioned, Sheppard et. al. (1988) conducted two meta-analyses of past research to examine the effectiveness of the Theory of Reasoned Action (or Fishbein's Behavioral Intention model) in predicting a variety of behaviors. In general, they found strong evidence for the model's predictive utility. The results indicated that,
based on 87 separate studies with a total sample of 11,566, a frequency-weighted average correlation for BI-B relationship was .53 (p < .01). Based on 87 separate studies with a total sample of 12,624, a similarly derived average correlation of .66 was found for the ATT + SN—>BI relationship (p < .001).

In spite of the substantial amount of supporting research, however, the model has been unable to explain some, or oftentimes a substantial, amount of the variance in behavioral intentions and behavior. Researchers have submitted numerous reasons for debate about the Theory of Reasoned Action's inability to more accurately account for these findings and other weaknesses of the model.

Critical evaluation of the Theory of Reasoned Action's limitations has primarily addressed two issues. These include: (1) changes in the model's causal structure and/or components, and (2) volitional versus involitional behavioral control. While this section attempts to address these two issues separately, their overlap is acknowledged and thus, the discussion of one does not completely exclude the other.

Concerns with Model's Causal Structure

A large amount of research has been targeted at the causal structure of the Theory of Reasoned Action and how adequately its components predict intentions and in turn, behavior. This research has led to modified models in which causal pathways and/or other variables have been added. Sarver (1983) and Liska (1984) have critically evaluated the TRA's causal structure and predictive validity. These critiques are important to discuss because they provide a relatively thorough review of the model's limitations that have been the concerns of numerous researchers. Therefore, these critiques are first presented followed by a brief discussion of specific changes in pathways and model variables proposed by other investigators.
Critical assessments of the TRA. In critically evaluating the Theory of Reasoned Action, Sarver (1983) raises several objections against Ajzen and Fishbein’s claim that the TRA is "designed to explain virtually any human behavior" (1980, p. 4). Sarver argues that Ajzen and Fishbein fail to consider several factors in proposing their causal model, particularly the "move" from intention to behavior. According to Sarver, the BI ---> B causal sequence may be blocked if the theory fails to incorporate the 'context of opportunity'. That is, an individual must have the opportunity to act in a manner consistent with his behavioral and normative beliefs, attitude, subjective norm, behavioral intention, etc. as they pertain to the behavior in question. Sarver (1984) also points out that even if the context of opportunity materializes, other factors may change the individual's intention, resulting in a blocked causal sequence (i.e. BI ---> B) and a failure of the behavior's execution.

Sarver (1983) also suggests that "contextual variables" may impact the "move" from intention to behavior, potentially interrupting the individual's performance of the behavior. Sarver defines "contextual variables" as "those variables which converge on the causal sequence at the point of opportunity, and which cannot be predicted from information gathered about other components of the sequence" (p. 158). For example, individual 'X' may intend to stay home and watch a television movie but be "moved" to go bowling with a good friend if the friend spontaneously arrives at the door of individual 'X'.

Sarver (1983) notes Ajzen and Fishbein's acknowledgement that: (1) unforeseen events may intervene between the intention and the behavior's execution, and (2) a great variety of events, such as sudden illness, natural disasters, loss of job, etc. can change an individual's intention even when the context of opportunity exists. However, he argues that the fleeting references made by Ajzen and Fishbein about
these 'unexpected' events do not take the place of a sustained and systematic consideration of these factors. Sarver (1983, p. 157) maintains that "any theory which claims to be a causal theory of human behavior must necessarily take account of factors which may impede, or even block, the very process the theory seeks to explain".

In another critical assessment of the TRA, Liska (1984) credits the Fishbein-Ajzen Behavioral Intention model for achieving some degree of conceptual order from the pool of attitude-behavior research that grew chaotically in the 1960's and 1970's. However, he (p. 62) identifies several "theoretical problems and issues generated by the parsimonious causal structure of the model". According to Liska, these problems and issues account for the lack of field research that supports the Theory of Reasoned Action. Liska discusses two major areas of concern: (1) the misspecification of the causal structure underlying relationships between attitudes, behavioral intentions, and behavior and (2) the misspecification of the causal structure underlying relationships between other variables, attitude, and behavior.

According to Liska (1984), the conceptual distinctions between attitude, behavioral intentions, and behavior as proposed in the Fishbein-Ajzen model are necessary and useful. However, he argues that while Fishbein and Ajzen's (1975) presentation of laboratory and field studies support their model, field research does not because of three possible misspecifications in the causal structure among these variables. A fourth misspecification is also offered by Liska but is discussed in the section addressing volitional versus involitional behavior.

First, contrary to the TRA's proposed structure, Liska claims that intentions do not completely mediate the effect of attitudes on behavior; rather the direct or unmediated effect of attitudes on behavior is often substantial and, in some cases,
greater than its mediated effect. He suggests that this may occur because intentions are frequently unstable and ill formed as well as oftentimes formed immediately before the individual behaves. Thus, attitude toward the behavior is proposed to directly affect behavior in addition to its indirect effect that is mediated by intention.

Second, Liska (1984) contends that attitudes do not completely mediate the effect of cognitions or beliefs on behavioral intentions. Instead, he suggests that belief structures may be too complex and individuals' cognitive processing capabilities may be too imperfect to effectively and efficiently capture and process all cognitions into an attitude. In addition, he proposes that changes in attitudes may lag behind changes in beliefs and hence, attitudes may not be effective in mediating all of the effects of beliefs on behavioral intention. Liska revises Fishbein and Ajzen's model to allow behavioral beliefs to directly affect intentions in addition to the indirect effect on behavioral intention that is mediated by attitude.

Lastly, Liska (1984) suggests that a reciprocal effects model, rather than the recursive model developed by Fishbein and Ajzen, may better depict the causal structure underlying the relationships among attitudes, intentions, and behavior. Based on empirical evidence in the dissonance, attribution, and behaviorism literatures, he argues that behavior affects attitudes. In addition, he proposes that if this effect is not taken into account, estimating procedures yield biased estimates of the model parameters. Therefore, Liska proposes a reciprocal effect model in which attitude directly affects both behavior and intention, behavioral intention directly affects behavior, and behavior directly affects, i.e. has a reciprocal effect on, attitudes.

In terms of the second major area of concern, i.e. the causal structure underlying relationships among attitudes, behavior, and other variables, Liska (1984) identifies
three issues not addressed in Fishbein and Ajzen's model. First, he contends that
Fishbein and Ajzen oversimplify the causal structure between attitudes and
subjective norms in their model. Liska accepts that the beliefs underlying both
attitudes and subjective norm are conceptually distinct and can be defined
independently. However, he argues that they are not causally independent.
Specifically, Liska proposes that while behavioral and normative beliefs determine
attitudes and subjective norms, respectively, these beliefs probably influence each
other. For example, beliefs about the consequences of behavior may be inferred
from others' expectations and vice versa. In addition, Liska proposes that subjective
norm and attitude may have an interactive, rather than an additive, effect on
behavior. Therefore, Liska suggests two revisions to the causal structure underlying
attitudes and subjective norms in the Fishbein model. These include: (1) effects of
behavioral and normative beliefs on both attitude and subjective norm as well on
each other, and (2) effects of attitude and subjective norm on behavioral intention
and behavior that are independent and additive as well as effects that are joint and
interactive.

Second, Liska (1984) recognizes that research has identified a large number of
"other" variables that influence subjective norms, attitudes, intention and behavior.
He claims, however, that Ajzen and Fishbein have treated the effects of these
variables as methodological nuisances. That is, the Fishbein-Ajzen model has no
mechanism for systematically incorporating the effects of "other", or contingency,
variables on components in the model. Liska argues that this approach maintains a
parsimonious model but ignores the conceptual significance of the problem. He
maintains that if weights vary systematically across subsamples of people, situations,
and behaviors, then incorporating a means to distinguish these subsamples can guide
research toward identifying the substantial conditions which distinguish them. Liska notes that contingency variables, incorporated as product terms, presents both a conceptual and pragmatic problem unless the number of variables is few. He suggests using standard data reduction techniques in identifying the underlying dimensions of contingency conditions in order to incorporate their effects into the model without generating an unparsimonious and difficult-to-estimate model. As an example, Liska describes the reduction of contingency variables in which attitude properties, such as centrality, intensity, salience, and certainty, are conceptualized as dimensions of an unmeasured general property, "attitude strength", which facilitates or mediates the impact of attitudes on behavior. The effect of contingency variables can also be incorporated into the effects of subjective norm on behavioral intention and behavior as well as the effect of behavioral intention on behavior.

Finally, Liska (1984) discusses the problem in conceptualizing certain variables, such as social structure and ecological factors, as background variables in the Fishbein-Ajzen model. In the case of social structure, he maintains that an individual's position in the structure determines, in part, the resources and opportunities allocated to the individual. Liska argues that social structure not only indirectly influences behavior by impacting an individual's attitudes, subjective norms, etc., but it also directly influences behavior in that it alters the medium, i.e. resources and opportunities, in which behavior's determinants are expressed. One example provided by Liska involves parental finances. Specifically, parents' finances (i.e. influencing the position in social structure) are probably just as important as their attitudes, subjective norms, and behavioral intentions in determining a child's educational attainment. As such, Liska proposes that
'resources' moderate the influence of behavioral intention on behavior and 'social structure' impacts attitude, subjective norm, and behavioral intention.

Liska's (1984) accumulative revision of the Fishbein/Ajzen model is one in which: (1) behavioral and normative beliefs determine both subjective norm and attitude, as well as each other; (2) contingency variables mediate, or interact with, the effect of attitude, subjective norm, and behavioral intention on behavior; (3) behavior impacts attitude, and (4) social structure influences behavioral and normative beliefs as well as behavioral intention.

In a study testing some of Liska's (1984) hypotheses, Davis (1985) used a rendition of Liska's model and found that social structure not only affected attitude and subjective norm but it also affected the availability of resources and opportunities, which, in turn, influenced behavior. Carpenter and Fleishman (1987) also found support for Liska's inclusion of a social structure variable, in terms of resources and opportunities, when they applied a modified-TRA model to the behavior of students' entry into college. Thus, it appears that a variable representing 'social structure' may be appropriate to include in Fishbein and Ajzen's intention model. Other pathways recommended by Liska remain to be tested.

Specific modifications in pathways and variables. Numerous investigators of the Theory of Reasoned Action have proposed modifying pathways or components of the model's causal structure. Some of these modifications were discussed in general terms in the critical assessments provided by Sarver (1983) and Liska (1984). This section describes in further detail some of the more commonly proposed modifications.
One pathway most frequently proposed for inclusion in the Theory of Reasoned Action stems from Bentler and Speckart's work (1979, 1981). These investigators demonstrated that attitudes' effects were not entirely mediated by behavioral intention in several behavioral domains of college students, including: drug use, dating, exercising, and studying. That is, a direct effect of attitudes on behavior was found in addition to its indirect effect. Other researchers have provided additional support for this pathway in several behavioral domains: blood donation (Zuckerman and Reis, 1978); mothers' infant-feeding intentions and behavior (Manstead et. al., 1983); and students' intentions to attend college (Carpenter and Fleishman, 1987).

Research refuting attitudes' direct effect on behavior has also been published (Bagozzi, 1981; Shimp and Kavas, 1984). Bagozzi (1981) suggests that Bentler and Speckart's results may be explained by: (1) demand characteristics or response errors since they used self-reported behavioral measures rather than actual measures of behavior and (2) the study of behaviors that were not fully volitional in nature and thus, inappropriate for using the TRA.

In two recent experimental studies involving a behavior presumed to be volitional in nature and thus, appropriate for study with the TRA, i.e. college students' reading behavior, Bagozzi and his colleagues (Bagozzi and Yi, 1989; Bagozzi et. al., 1990) have found support for a direct effect of attitude on behavioral intention. Bagozzi and Yi (1989) manipulated the degree of intention formation by assigning students to two experimental conditions: (1) a distraction task, meant to lead to ill-formed intentions, and (2) a focused task that was meant to lead to well-formed intentions. Results of this study indicated that attitudes did directly affect behavior when behavioral intentions were not well formed but did not affect
behavior when intentions were well formed. Bagozzi et. al. (1990) found similar results in studying the same behavior when the level of effort required for performing the behavior was manipulated. Specifically, attitude did directly affect behavior when a low level of effort was required to perform the behavior; however, this path was not supported when the level of effort was high.

The explanation offered for the findings of both studies are similar. Bagozzi and Yi (1989) propose that when an individual gives much thought to the act, intentions will be well-formed and thus, be more likely to reflect attitudes. On the other hand, when an individual gives little thought to the decision process, intentions will be ill-formed and less likely to reflect attitudes or adequately channel the effect of attitudes on behavior. Bagozzi et. al. (1990) suggest that their results are explained by the processes in which individuals participate in conscious thought processes to arrive at their intention to behave. Specifically, they suggest that behaviors requiring much effort are determined largely by a deliberate decision-making process and thus, intentions fully mediate the effects of attitude on behavior. However, for behaviors requiring little effort, the formation of intentions is not based on deliberate cognitive processes. As such, intentions do not fully mediate the effects of attitude on behavior; rather, attitude directly influences behavior.

In sum, evidence exists to suggest that attitude may directly or indirectly affect behavior. The most recent research conducted by Bagozzi and his colleagues has proceeded beyond the question of whether attitude does or does not have a direct effect on behavior. Instead, this research has addressed the question of 'when' does attitude directly impacts behavior.

Researchers have proposed other modifications to the TRA by including additional variables in the model. One popular variable for inclusion has been prior
or past behavior. Bentler and Speckart (1979) found a significant effect of past behavior on both behavioral intention and behavior for three drug-taking behaviors. A later study by Bentler and Speckart (1981) supported a significant effect of past behavior on attitude for one of three behavioral domains. Bagozzi (1981) found that past behavior attenuated the ATT→BI and BI→B relationships when it was included as an explanatory variable for blood donating behavior. Specifically, past behavior did not directly influence a proximal measure of behavior but its impact was mediated by behavioral intention. Past behavior did have a direct effect, however, on a measure of distal behavior. Other researchers have provided additional support for the effect of past behavior on behavioral intention and behavior including: attendance at art events (Crosby and Muehling, 1983), students' class attendance (Fredricks and Dossett, 1983), mothers' infant-feeding behavior (Manstead et. al., 1983), weight loss (Bagozzi and Warshaw, 1990), and cancer self-exam (Steffen and Gruber, 1991).

Two primary explanations for past behavior's effect on future behavior can be offered. First, when past behavior occurs frequently, behavior becomes repetitive, or habitual. In this case, the prediction of future behavior is not appropriate for study with the TRA; rather, past behavior is the best predictor of future behavior. Another explanation for past behavior's effect on future behavioral performance involves the inadequacy of the TRA in predicting human behavior. Since the TRA has not been able to account for all of the variance in behavioral intentions and behavior, it has been suggested that factors not currently captured in the TRA's components are exerting their influence in the past behavior measure.

Another modification to the Theory of Reasoned Action that has been widely debated is the use of behavioral expectation (BE) versus behavioral intentions (BI)
measures. According to Warshaw and Davis (1985), in many cases, past research has failed to distinguish a person's intent to perform a given behavior (e.g. "Do you intend to do 'X'?") from his or her subjective estimate of actually performing the behavior (e.g. "Are you likely to do 'X'?" or "Will you do 'X'? "). On the other hand, the authors maintain that subjects have been shown to differ in their responses to questions regarding their intentions and their estimates or expectations.

The meta-analysis conducted by Sheppard et. al. (1988) confirms that the two types of measures have been used interchangeably in past research using the TRA. Results of the meta-analysis indicated that the ATT + SN --> BI relationship was stronger than the ATT + SN --> BE relationship whereas the BE --> B relationship was marginally stronger than the BI --> B relationship. Sheppard et. al. (1988, p. 339) suggest that "intention and estimation apparently are distinct concepts in people's minds, and meaningful differences in the determinants and uses of such concepts also are indeed likely." Thus, it appears prudent to recognize these differences in using the model to study human behavior and in developing the study's measurement instrument. Although this issue could be discussed in further detail, it is not the focus of this investigation and thus, will be tabled at this time. It is briefly readdressed, however, in the literature reviewing the Theory of Planned Behavior.

In addition to the variables and pathways proposed by Sarver (1983), Liska (1984) and the ones discussed above, many others have been proposed for inclusion in the Theory of Reasoned Action, such as: (1) habits (Kahle et. al., 1983), (2) moral norms or 'personal norms' (Schwartz and Tessler, 1972; Pomazal and Brown, 1977; Zuckerman and Reis, 1978; Biddle et. al., 1987; Prestholdt et. al., 1987), (3) investment (Koslowsky et. al., 1988), (4) self-efficacy expectations (McCaul et. al.,
1988; Brubaker and Fowler, 1990), (5) self-concept (Carpenter and Fleishman, 1987), and (6) perceived behavioral control (Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1988; Ajzen, 1991). With the exception of "self-efficacy expectations" and "perceived behavioral control" that are included in Bandura's self-efficacy theory and Ajzen's Theory of Planned Behavior, respectively, study and support of these variables have been relatively minimal.

In summary, critical assessments of the Theory of Reasoned Action have identified major weaknesses in the model's causal structure. Some of these criticisms have argued that the model needs to include variables such as "contingency factors", "social structure", "past behavior", "self-efficacy", and "perceived behavioral control" in the model. Some criticisms have resulted in proposing additional pathways among components of the TRA. For example, researchers have suggested that attitudes directly impact behavior, and behavioral and normative beliefs are interactive in determining attitude and subjective norm. Recent research has focused on determining when attitude directly impacts behavior, i.e. moderate the intention-->behavior pathway, or relationship. Many of these criticisms overlap with the topic discussed in the next section. This topic, adds further fuel to the debate of TRA's usefulness in predicting and explaining human behavior.

Volitional versus involitional behavior. As stated previously, the Theory of Reasoned Action applies to behaviors that are under an individual's volitional control. Volitional control can be defined as behavior that an individual can decide at will to perform or to not perform (Ajzen, 1988). The more the behavior is contingent on the presence of appropriate resources and opportunities, such as skills,
abilities, cooperation of others, etc., the less it is under volitional control (Ajzen and Madden, 1986). In terms of physicians' spontaneous reporting behavior, it is reasonable to expect that this behavior is not completely volitional since it may depend on the cooperation of the patient, the availability of resources (e.g. report forms) and opportunities (time), assistance from other health care professionals in the ADE's follow-up, etc.

Until relatively recently, Ajzen and Fishbein (1980, p. 5) have maintained that "most actions of social relevance are under volitional control". However, both critiques offered by Sarver (1983) and Liska (1984) suggest that in making this assumption, Ajzen and Fishbein have overlooked a major factor important for predicting human behavior. Liska (1984, p. 63) provides the following argument:

"{Fishbein and Ajzen's} position is hard to understand. For while a wide variety of behaviors appear to be largely under volitional control, at least given present social arrangements, an equally wide variety appear to require abilities, skills, and social cooperation and would seem to be of considerable interest to social scientists, perhaps even more so than behavior under volitional control".

Liska (1984) faults the Theory of Reasoned Action because its use is restricted to volitional behavior, appearing to create a false dichotomy of behavior that is categorized as either volitional or involitional. He argues that little is gained by this dichotomy or by building different models for each. Alternatively, he proposes a continuum of behavioral control in which involution, or lack of control, anchors one end and volition anchors the other. Contingent variables that affect an individual's allocation of resources, such as position in social structure or ecological factors, mediate the formation of his attitudes, subjective norm, and intentions as well as
directly impacts his behavior. Thus, Liska suggests that contingent variables should be incorporated into the TRA to address the issue of nonvolitional behavior.

Although Sarver (1983) does not specifically use the "volitional versus involitional behavior" terminology, his critique of the Theory of Reasoned Action also addresses this issue. As previously discussed, Sarver's (1983, p. 156) arguments that the TRA "cannot be seriously regarded as a tool for the prediction and understanding of human behavior" are based on the model's failure to incorporate the "context of opportunity" or "contextual variables" which may block the move from (or causal sequence of) intention to behavior. These variables represent, in fact, factors that may interfere with a behavior's enactment and therefore, their existence reflect the extent to which the behavior is involitional.

The issue of involitional versus volitional behavior is not a recent concern or one applicable only to the Theory of Reasoned Action. It has been addressed by other researchers' models that incorporate factors facilitating or mediating a behavior's enactment. Triandis (1977) has proposed a model in which the probability of an action is a function of an organism's or individual's habit and the intention to perform a given behavior, both multiplied by "facilitating conditions" or factors. These factors include the individual's knowledge, ability, and motivation to perform the behavior, as well as environmental or task factors that may influence the ease or difficulty of the activity. Intention is proposed to be a function of three weighted components, namely social, affective, and cognitive factors. The affective and cognitive factors most closely resemble the TRA's expectancy-value attitude. The social component includes norms, roles, self-concept, and interpersonal contracts. Hence, the Triandis model addresses some of issues debated by researchers critiquing the Theory of Reasoned Action. Its weakness, however, is that Triandis'
model is less parsimonious and has received less empirical attention or support than
the TRA.

Two other theoretical models that have addressed the issue of volitional versus
involitional behavior merit a brief discussion. Kuhl (1984, 1985) also contends that
volition or self-regulatory control is important for explaining the BI→B pathway.
In his theory of "action control", he includes the individual's perceived ability to
successfully control the intention's execution with the strengths of competing
tendencies, the social pressure to engage in competing activities, and the current
degree of state-orientation (change-preventing) in determining the intention's
stability. Lastly, Bandura's (1977, 1982) self-efficacy theory considers an
individual's expectation or belief about his or her ability to perform a given
behavior. This theory is addressed in further detail in the section discussing the
Theory of Planned Behavior.

In summary, a major criticism of the Theory of Reasoned Action has been its
inapplicability to behaviors that are not completely volitional in nature. Although
Ajzen and Fishbein have claimed, until recently, that most behaviors of social
relevance or research interest are under volitional control, literature suggests that
their assumption is erroneous. Several researchers have proposed mechanisms and
theoretical models that incorporate an indicator of the extent to which a behavior is
under volitional control. However, these models have received less empirical
attention in the sociology, psychology, marketing, and health care literatures and in
general, are less parsimonious than the Theory of Reasoned Action. The TRA, as a
model for predicting human behavior, then, has the advantages of extensive
empirical support and parsimony. In spite of these advantages, a need exists to
incorporate an indicator in the TRA that reflects the extent to which an individual
controls his performing a given behavior while maintaining the parsimony of the model. Recent research has addressed this issue and is further addressed in this investigation.

**TRA: Concluding Remarks**

Over the past two decades, the Theory of Reasoned Action has emerged as a popular attitude-behavior model for predicting and explaining human behavior. Its popularity is based on its parsimonious nature, ease of use, and predictive utility. Other research has validated the model as a whole as well as examined the validity and reliability of the model's components and measurement scales. These research efforts, combined with Fishbein and Ajzen's recommendations for questionnaire development, have provided investigators with a model that is easy to apply and provides relatively valid and reliable results.

Although the TRA has explained a significant amount of variance in sociology, psychology, marketing, and health care studies, the amount of unexplained variance remaining indicates that the model is most likely excluding factors that could improve its predictive utility. In addition, research has suggested that the structures underlying the expectancy-value and normative belief-motivation to comply composites have been oversimplified, thus misrepresenting the relationships between the model's components.

Critical evaluation of the Theory of Reasoned Action as a causal model of human behavior has led to other issues of debate. The major issues have included: (1) the extent to which involitional behavior exists, (2) the TRA's inability to predict involitional behavior, (3) the TRA's implication that behavior can be simply dichotomized into volitional or involitional behavior and separate models are built
for each, (4) the inclusion of other variables in the model such as "past behavior", "contextual variables", "context of opportunity", "social structure" that allocates resources and opportunities, etc., to improve its predictive utility, and (5) the addition of causal pathways to the model that improve the model's predictive utility, such as attitude's direct effect on behavior, the interactive effect of subjective norm and attitude on intention, behavior's effect on attitudes, etc.

Clearly, the need to reexamine the causal structure of the relationships between the Theory of Reasoned Action's components is supported. In addition, the TRA needs to be reassessed in terms of other variables that when added to the model may increase the model's predictive utility. However, the incorporation of variables and/or pathways must be theoretically justifiable and not indiscriminate. Decisions to expand or change an established model should balance gains and losses. That is, a gain in an amended model's predictive capabilities needs to be greater than or equal to its loss in parsimony. Furthermore, these gains should be demonstrated in a number of empirical studies so that the theoretical basis of the model is well supported.

The literature reviewed in this section has identified several issues of which further research can contribute to the theoretical framework necessary for developing or modifying a model such as the Theory of Reasoned Action. First and foremost, a model that can explain and predict human behavior that is not fully under an individual's control is needed. Ideally, this model should be parsimonious, easily applied, and able to predict behavior accurately across a wide number of individuals, situations, and behaviors. Second, the role of past behavior in determining behavioral intention and behavior warrants further attention. In addition, research that examines the role of other variables, such as "self-efficacy" and "perceived
behavioral control" on the formation of intentions and the performance of behavior is needed. Finally, causal pathways, specifically the ATT --> B relationship, needs further investigation, in terms of when and under what conditions this pathway occurs. "involitional behavior". The TRA's successor, the Theory of Planned Behavior, and this investigation addresses many of these concerns.

The Theory of Planned Behavior

Introduced to the literature in the mid 1980's, the Theory of Planned Behavior (TPB) is an extension of the TRA. With its arrival, Ajzen (1985, p. 24) acknowledges that involitional behavior is more the norm than the exception:

"Some behaviors are more likely to present problems of control than others, but we can never be absolutely certain that we will be in a position to carry out our intentions. Viewed in this light it becomes clear that, strictly speaking, every intended behavior is a goal whose attainment is subject to some degree of uncertainty".

Ajzen's change of heart regarding the frequency in which involitional behavior occurs and its newfound importance as an issue may have been motivated by critics of the Theory of Reasoned Action and the attention it had received in other theoretical models.

Similar to the TRA, the Theory of Planned Behavior assumes that an individual is a rational actor and his intention and subsequent behavior can be predicted by a small set of constructs. Furthermore, the model assumes that the influence of all variables outside the model has no direct effect on behavior but may indirectly impact behavior via the model's components. Contrary to the TRA, however, the
theory postulates a third independent determinant of behavioral intention: perceived behavioral control.

The following discussion of the Theory of Planned Behavior follows the general approach undertaken in reviewing the TRA. First, the TPB's components and their underlying causal structure, as defined by Ajzen and his colleagues, are discussed. The second section briefly discusses validity and reliability issues as they pertain to the TPB. Next, applications of the model and evaluation of the empirical support are provided. Lastly, concluding remarks about the Theory of Planned Behavior as a model for predicting and explaining human behavior are presented.

TPB: Components and Causal Structure

This section examines the components of the Theory of Planned Behavior and the causal structure underlying the relationships between them as described in literature published by Ajzen and his colleagues. First, the model's overall structure, as currently defined, is described in terms of its components and the causal relationships among them. Next, the conceptual status of the perceived behavioral control construct and issues pertaining to its conceptual process are discussed.

Overall Model Structure: Background

Previous discussion suggests that the Theory of Reasoned Action, which relies on intention as the sole predictor of behavior, will be insufficient when an individual lacks control over performing the behavior. Obviously, many factors, both internal and external to the individual, can interfere with the behavior's execution by inhibiting or facilitating the individual's control over the behavior.
Internal factors are defined as characteristics of the individual and include the individual's locus or attribution of control, information, skills, abilities, willpower or strength of character, forgetfulness, emotions, compulsions, adequate planning, etc. On the other hand, external factors are situational or environmental variables that impinge on the individual's control such as time, resources, opportunity, reliance of behavioral performance on other people's cooperation or on other events' occurrence (Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1988). The Theory of Planned Behavior attempts to incorporate the impact of these facilitating or inhibiting factors on intention and behavior.

Consistent with the TRA, the central element in the Theory of Planned Behavior is the individual's intention to perform the given behavior. Although the original derivation of the TPB (Ajzen, 1988, p. 132) interpreted 'intention' as the "intention to try performing a certain behavior", Beck and Ajzen (1990) report that research has supported dropping the cumbersome 'trying' measures for ones pertaining to actual behavioral performance.

Contrary to the TRA, the TPB proposes three conceptually independent determinants of behavioral intention. The first two, attitude toward the behavior (ATT) and subjective norm (SN), are identical to the determinants of intention in the TRA and have been previously defined. The third and novel determinant is 'perceived behavioral control'.

Perceived behavioral control (PBC) refers to "the perceived ease or difficulty of performing the behavior and it is assumed to reflect past experience as well as anticipated impediments and obstacles" (Ajzen, 1988, p. 132). The TPB postulates that among the beliefs that determine subjective norm and attitude toward the behavior, an individual possesses beliefs about the presence or absence of resources
and opportunities required to perform the behavior. These beliefs, referred to as "control beliefs", reflect factors, both internal and external to the individual, that influence the individual's perception of control over performing the behavior. The more resources and opportunities an individual thinks he possesses and the fewer the obstacles he anticipates, the greater the individual's perception of control over the behavior should be.

Control beliefs can be separated from the beliefs underlying attitude and subjective norm to provide the basis for perceptions of behavioral control. Although these beliefs are presumably separate, they may correlate with behavioral and normative beliefs because the factors that influence one set of beliefs (e.g. behavioral) may also influence the other sets (e.g. normative and control). Similar to normative and behavioral beliefs, an individual's perception of behavioral control is based on salient beliefs about control.

According to Ajzen and his colleagues (Ajzen and Madden, 1986; Ajzen, 1987; Ajzen, 1988), control beliefs may be based on the individual's prior experience with the behavior. In addition, they may be indirectly influenced by second-hand information about the behavior, the experiences of friends or others, the media, or other factors that increase or decrease the perceived difficulty of performing the behavior. Generally speaking, then, control beliefs may inaccurately reflect an individual's actual control if: (1) the individual has little direct or indirect information about performing the behavior, (2) the required resources and opportunities have changed, or (3) new or unfamiliar factors have entered the situation.

The Theory of Planned Behavior uses an individual's perception of control over a behavior rather than his actual control for several reasons. First, identifying an
individual's actual control over performing a given behavior would be difficult, if not impossible, to assess because factors that can interfere with an intended behavior are often accidental in nature and not anticipated. Second, even if the factors could be identified, determining whether an individual possesses them or would be influenced by them, particularly internal ones such as skills and ability, would most likely be unknown until the individual attempted the behavior. A measure of an individual's perception of control is possible to measure, however, and may accurately reflect his actual control over the behavior of question.

According to the Theory of Planned Behavior (see Figure 3), perceived behavioral control has both motivational and nonmotivational implications for intentions and behavior. In terms of motivational effects, if an individual believes that he lacks the factors, either internal or external to the individual, necessary to perform a given behavior, he is unlikely to form strong intentions to engage in the behavior even if he has a favorable attitude and subjective norm with respect to the behavior. In general, the more favorable the individual's attitude and subjective norm with respect to a given behavior, and the greater the individual perceives his control over performing the behavior, the stronger the individual's intention to perform the behavior should be. The Theory of Planned Behavior, then, proposes that perceived behavioral control can indirectly impact behavior by influencing an individual's motivation or intention to perform a given behavior.

The degree of success to which a given behavior can be predicted depends not only on the individual's intention but also on nonmotivational effects. The internal and external factors (i.e. resources and opportunities) that influence an individual's intention can also directly impair or facilitate an individual's actual control over performing a given behavior, regardless of the individual's intention. To the extent
Figure 3: The Theory of Planned Behavior (Ajzen, 1988, p.133)
that an individual intends to perform the behavior and has adequate behavioral control, he will succeed in performing the behavior. However, if the individual's perception of control over the behavior is not realistic, i.e. it does not accurately reflect actual control, the measure of PBC will not significantly add to the prediction of behavior. Furthermore, if the behavior under study is entirely volitional in nature, the individual's perception of control is not an important consideration in forming his intention. In this case, the concept of perceived behavioral control is essentially irrelevant in the prediction of behavior and the TPB reduces to the TRA.

In summary, the Theory of Planned Behavior is proposed to explain and predict behaviors that are not completely under an individual's control. As illustrated in Figure 3, the model includes three determinants of intention: attitude, subjective norm, and perceived behavioral control. In turn, each of these constructs is determined by a set of beliefs: "behavioral", "normative", and "control" beliefs. Although "control beliefs" can be separated from the behavioral and normative beliefs underlying attitude and subjective norm, respectively, some overlap among the three constructs is anticipated and thus, consistent with the TRA, the Theory of Planned Behavior allows them to correlate.

Perceived behavioral control, the novel construct in the model, can play both motivational and nonmotivational roles in the model. In terms of the motivational role, an individual's beliefs about the requisite resources and opportunities will influence the strength of his intention to perform the behavior. In terms of the construct's direct impact on behavior, i.e. its nonmotivational implication, the PBC-B pathway only emerges when: (1) factors, either internal or external to the individual, directly impair or facilitate the individual's actual control over performing the behavior, regardless of his intention, and (2) the individual's
perception of behavioral control agrees to some degree of accuracy with his actual control. If the behavior of interest is completely volitional, the PBC concept becomes largely irrelevant and it drops out of the model, reducing to its more parsimonious model, the Theory of Reasoned Action. If the individual's perception of control does not accurately reflect his actual control, perceived behavioral control can influence behavioral intention but will add little to the prediction of behavior.

PBC: Current Conceptualization and Conceptual Issues

As previously defined, perceived behavioral control is an individual's belief about how easy or difficult performance of the behavior is expected to be and is assumed to reflect past experience as well as anticipated obstacles or impediments (Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1987; Ajzen, 1988). Similar to Liska (1984), Ajzen (1987; 1988) characterizes PBC as a continuum of perceived control over behavior, ranging from no control at one end of the spectrum to complete control at the other end. The closer the behavior lies to the continuum's "no control" end, the greater is the importance of considering the individual's perceived behavioral control in determining intention and behavior, and the greater the inadequacy of the TRA in predicting the behavior under study. On the other hand, the closer the behavior lies to the "complete control" end, the less important it is to consider the individual's perceived behavioral control. In the latter case, the TRA may predict intention and behavior with a relative degree of accuracy. Ajzen proposes that the majority of behaviors probably lie somewhere in-between these two extremes.

According to Ajzen and his colleagues (Ajzen and Madden, 1986, Ajzen, 1987; Ajzen 1988), the issue of an individual's actual control over behavior has not been
limited to those investigators proposing "facilitating conditions", "resources", etc. Rather, researchers have considered the effect of perceived control over human judgement and behavior for decades. For example, one group of models have focused on Rotter's (1966) concept of internal-external locus of control. This concept refers to the generalized belief that an individual's outcomes are under the control of either one's own behavior (internal locus of control) or factors such as chance or powerful others (external locus of control). Ajzen (1988) claims that Rotter's locus of control significantly differs conceptually from perceived behavioral control in that an individual's locus of control is a generalized expectancy that remains stable over time and situations whereas PBC purportedly varies over time and situations. Furthermore, Ajzen argues that studies using generalized expectancy control measures, such as locus of control, have provided weak and inconsistent results in predicting behaviors.

Further discussion of the current status of PBC's conceptualization involves addressing several issues. For example, some investigators have voiced confusion about inconsistencies in Ajzen and his colleagues' conceptualization of perceived behavioral control. This confusion as well as other issues pertaining to the construct's current level of conceptualization are addressed in the following discussion and include: (1) the conceptual basis for perceived behavioral control, (2) the determinants of perceived behavioral control, and (3) the conceptual distinction between past behavior and perceived behavioral control. Finally, some concluding remarks with respect to the conceptualization of perceived behavioral control are presented.

PBC: conceptual basis. As expected with any conceptual process, the conceptualization of perceived behavioral control has evolved since its introduction
to the literature. In some researchers' eyes, this evolitional process, particularly in its early stages, has led to confusion with respect to the concept's specific role in predicting human behavior. Fishbein and Stasson (1990, p. 196) have eloquently summarized this point:

"....important questions about the meaning and measurement of perceived control have been raised. Does perceived control have to do with (a) perceptions that performance of a behavior (or attainment of a goal) is influenced by other people or events, (b) Bandura's (1977, 1982) notions of self-efficacy (i.e. I can do it if I want to) or (c) Triandis' (1977) concept of facilitating factors (i.e. performing this behavior is difficult, complex, time consuming)? While Ajzen's (1985) original discussion of perceived control seemed to reflect all three of these meanings, his more recent writings (e.g. Ajzen, 1987) seem to focus more on facilitating factors. Clearly, this is an issue that must be resolved before perceived control can become a viable construct in any theory".

The above citation accurately recognizes the theories or models which have seemingly influenced the conceptualization of perceived behavioral control. As previously noted, Ajzen and his colleagues (Ajzen, 1985; Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1987) have frequently cited Triandis' "facilitating factors" (1977), "resources" by Liska (1984), Sarver's (1983) "context of opportunity", and Kuhl's "action control" (1985) in their discussions of the PBC construct.

In spite of voiced confusion regarding the conceptual basis of perceived behavioral control and its role in a model of human behavior, the literature provided by Ajzen and his colleagues (Ajzen, 1985; Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1987; Ajzen, 1988) has been relatively consistent in citing Bandura's (1977, 1982) concept of "self-efficacy beliefs" as most similar to the perceived
behavioral control concept. The proposed link between these two concepts is described in the following excerpt (Ajzen and Madden, 1986, p. 457):

"Most similar to the present use of perceived behavioral control, however, is Bandura's (1977, 1982) concept of self-efficacy beliefs. Bandura and his associates (e.g., Bandura, Adams, and Beyer, 1977; Bandura, Adams, Hardy, and Howells, 1980) have provided evidence showing that people's behavior is strongly influenced by their confidence in their ability to perform it (i.e. by perceived behavioral control). The theory of planned behavior places this construct within a more general framework of the relations among beliefs, attitudes, intentions, and behavior."

Ajzen's (1991) most recent work is consistent with his earlier discussion regarding the conceptual similarity between perceived behavioral control and Bandura's concept of self-efficacy. In addition, Ajzen reaffirms the strength of including a "perceived control" component in a more general model, such as the Theory of Planned Behavior, that can represent the relations among beliefs, attitudes, and behavior.

**Determinants of PBC.** Since the introduction of the Theory of Planned Behavior, Ajzen and his colleagues have consistently maintained that a set of beliefs about the availability of requisite resources and opportunities provide the basis for, or underlie, an individual's perception of control over a given behavior (Ajzen, 1985; Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1987). This set of beliefs, referred to as "control beliefs", have been previously defined as beliefs about factors, both internal and external to the individual, that influence the individual's perception of control over performing the behavior.
In their study of the Theory of Planned Behavior, Beck and Ajzen (1991, p. 287-288) note that "the {TPB} also deals with the antecedents of attitude, subjective norms, and perceived behavioral control. These antecedents have to do with various beliefs about the behavior that constitute the informational foundation on which intentions and actions are assumed to rest." Although these beliefs were reportedly assessed, further information regarding their content, analysis, or use was not provided in this article or any literature published to date.

The Theory of Reasoned Action defines the antecedents of both attitude and subjective norm as expectancy-value and normative belief-motivation to comply composites. These composites remain the antecedents of attitude and subjective norm in the model's successor, the Theory of Planned Behavior (Ajzen, 1988). The antecedent of perceived behavioral control, however, is not clearly defined. Based on currently published research, it appears that the set of "control beliefs", as defined by Ajzen and his colleagues, is viewed as the determinant, or antecedent, of perceived behavioral control. Unfortunately, the exact nature of these beliefs is unclear. This section describes the measures of perceived behavioral control used by Ajzen and his colleagues, as well as other investigators, in an effort to understand the operationalization of the construct and its conceptual basis. A more complete description and comparison of the studies' results are provided in a following section.

Empirical studies published by Ajzen and his colleagues have operationalized the perceived behavioral control construct with one or two of the following methods: (1) a direct measure which includes questions pertaining to the individual's global perception of behavioral control (hereafter referred to as a "direct PBC measure"), and (2) a less direct measure consisting of questions that pertain to the individual's
beliefs about the frequency or likelihood of factors occurring that may influence his performing the behavior via interfering or facilitating (hereafter referred to as a "belief-based PBC measure").

In two studies conducted by Ajzen and his colleagues, only a direct PBC measure was developed and included in the data collection instrument. Schifter and Ajzen (1985, p. 845) used two questions in their study of female college students' intentions and behavior with respect to weight loss. Students were asked to respond on a scale, ranging from 0 to 100, to: (1) "the likelihood that if you try you will manage to reduce weight over the next six weeks"; and (2) "your best estimate that an attempt on your part to reduce weight over the next six weeks would be successful". The average of the two-item direct measure ($r = .63$) served as the measure of perceived control. Study results indicated that perceived behavioral control, as well as attitude and subjective norm, was significant predictor of women's intention to reduce weight ($p < .01$).

In a study conducted by Beck and Ajzen (1991, p. 293), the direct PBC measure consisted of four items for each of three college students' behaviors: cheating on a test, shoplifting, and lying to get out of assignments. For each behavior, students were asked to respond to the four items on a seven-point semantic differential-type scale, including: (1) "For me to cheat on a test or exam is ... easy/difficult"; (2) "If I want to, I can cheat on a test or exam ... true/false"; (3) "I can imagine times when I might cheat on a test or exam even if I hadn't planned to ... likely/unlikely"; and (4) "Even if I had a good reason, I could not bring myself to cheat on a test or exam ... likely/unlikely". The PBC measure was generated by summing the appropriate set of responses and the average interitem correlations were .34, .48, and .34 for cheating, shoplifting, and lying, respectively. Study results indicated
that the measure of perceived behavioral control was a significant predictor of intentions for each of the three behaviors ($p < .05$). Attitude, but not subjective norm, also significantly predicted cheating and shoplifting whereas subjective norm, but not attitude, also a significant predictor of lying.

Ajzen and Madden (1986), using the most rigorous measure to date, developed both direct and belief-based PBC measures in two studies of college students' behaviors: class attendance (Study 1) and obtaining an "A" in a specific course (Study 2). The direct measure applied in Study 1 (p. 462) consisted of summing students' responses from the following three questions posed at separate points in the questionnaire: (1) "How much control do you have over whether you do or do not attend this class every session ... complete control/very little control"; (2) "For me to attend every session of this class is ... easy/difficult"; and (3) "If I wanted to I could easily attend this class every session ... extremely likely/extremely unlikely".

Similar to the first study, the direct PBC measure in Study 2 (p. 467) summed the responses to the following five items: (1) "It is mostly up to me whether or not I get an 'A' in this course ... true/false", (2) "If I wanted to I could get an 'A' in this course ... likely/unlikely;" (3) "There is very little I can do to make sure that I get an 'A' in this course ... agree/disagree"; (4) "For me to get an 'A' in this course is ... easy/difficult"; and (5) "How much control do you have over whether you do or do not get an 'A' in this course ... complete control/very little control". Responses to the items were found, via a confirmatory factor analysis, to form a unidimensional scale in both experiments, thus supporting the items' summation to form one direct indicator of PBC. The measures' coefficient alpha were .74, .69, and .79 for Study 1, Study 2/wave 1, and Study 2/wave 2, respectively. Study results found that the direct PBC measure, in addition to the direct ATT and SN
measures, was a significant predictor of intention in Study 1 (p < .01). Results from Study 2/waves 1 and 2 found similar results for the perceived behavioral control and attitude measures (p < .01). However, the direct subjective norm measure was not a significant predictor of intention.

Belief-based PBC measures were also developed by Ajzen and Madden (1986) for both Studies 1 and 2. In the first study, students were asked to rate, on a seven-point scale, their beliefs about the frequency in which ten factors (identified in a pilot study) might conflict with their attending class. The exact wording of the scales' endpoints depended on the factor involved but included ranges (p. 462) such as "many events/none at all", and "never/frequently". In Study 2, students responded to the same type of scale for eight belief statements pertaining to facilitating or inhibiting factors (identified in a pilot study) that might influence their getting an "A" in a specified class. Again, anchors for each factor's scale was contingent on the nature of the factor but included pairs (p. 467) such as "frequently/never" and "likely/unlikely". Within each experiment, the belief-based measures were summed to provide one PBC indicator. The reliability of the belief-based measures were .73, .54, and .62 for Study 1, Study 2/wave 1 and Study 2/wave 2, respectively. In terms of significant predictors of intentions when belief-based measures were used for ATT, SN, and PBC, all were significant in Study 1 (p < .01). The authors report testing the theoretical models in the second study with direct measures only because the belief-based measures were highly correlated with the direct measures.

A closer look at the approach taken by Ajzen and Madden (1986) for operationalizing the set of "control beliefs" uncovers a potential concern with the current conceptualization of perceived behavioral control. Specifically, their use of
different types of scales for measuring these beliefs confuse the conceptual meaning of the construct. The authors did not address whether or not a frequency scale was equivalent to a likelihood scale but used both types of scales in the same belief-based measure as if they were interchangeable. However, subtle similarities and differences between the two types of scales are indicative of subtle similarities and differences in the approach taken to conceptualize "control beliefs" and thus, perceived behavioral control.

A likelihood scale provides information about the chance of an event occurring. More specifically, this scale characterizes the possibility or expectance of an event occurring and to what degree or extent (measured by the scale's categories) this possibility exists. A frequency scale is similar to a likelihood scale in that if a subject responds that an event occurs 'frequently', the likelihood of the event occurring is probably very high. Likewise, if an event is described as 'never' occurring, the possibility of the event occurring is probably very low. The differences between the two types of scales, however, should be more noticeable when interpreting the scales' categories. Specifically, a frequency scale differs from the likelihood scale in that the degree or extent, measured by the scale's categories, refers to how often the event occurs rather than how possible the event's occurrence is. Therefore, some similarities exist between the two types of scales because an individual responding to the frequency scale might respond relatively similarly to a likelihood scale. However, the two types of scales differ conceptually and thus, may provide mixed or less interpretable results if used interchangeably.

The discussion above might help explain an interesting finding in Ajzen and Madden's (1986) measures. Specifically, the coefficient alpha attained with the measure that appears to have consisted solely of frequency scales (alpha = .73) was
higher than the coefficients obtained with the measures that reportedly mixed frequency and likelihood scales (Wave 1 = .54; Wave 2 = .62). While the difference in the measures' internal consistency may be due to the number of items included in each measure, i.e. the ten-item scale had a higher alpha coefficient than the eight-item scale, the difference may also be due to unclear conceptualization and subsequent operationalization of "control beliefs". In sum, the operationalization of the belief-based PBC measure may need clarification. That is, the construct's definition probably needs to address whether the individual's "control beliefs" pertain to the likelihood or the frequency of the influencing factors' occurrence. Although the two sets of anchors may provide similar responses in many cases, they differ conceptually and as a result, may have led to enough dissimilar responses to adequately measure the perceived behavioral control construct. This concern is further addressed in the dissertation's development of perceived behavioral control and the model used in this investigation to study physicians' intent to report serious adverse drug events to the FDA.

The literature includes additional investigations of the Theory of Planned Behavior that have operationalized the perceived behavioral control construct. However, these investigations have developed measures consistent with the direct PBC measure used by Ajzen and his colleagues (Schifter and Ajzen, 1985; Ajzen and Madden, 1986; and Beck and Ajzen, 1991). Generally speaking, the measures used by other investigators have included one to four items, summed to generate a direct PBC measure. Tables 1 and 2 summarize the PBC measures used in the studies discussed thus far, in terms of the type of scale and its internal consistency. Since three studies used only one-item measures, evaluating the internal consistency of these measures is not an option. The studies that did develop multi-item scales
<table>
<thead>
<tr>
<th>INVESTIGATORS</th>
<th>BEHAVIOR</th>
<th>MEASURE</th>
<th>SCALE&lt;sup&gt;a&lt;/sup&gt;</th>
<th>ITEMS/RELIABILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schifter &amp; Ajzen (1985)</td>
<td>Weight loss</td>
<td>Global</td>
<td>0=100 Likelihood</td>
<td>2 averaged/ r=.63</td>
</tr>
<tr>
<td>Ajzen &amp; Madden (1986)</td>
<td>Attending</td>
<td>Global</td>
<td>Unspecified</td>
<td></td>
</tr>
<tr>
<td></td>
<td>class</td>
<td></td>
<td>semantic</td>
<td>3 summed/ca&lt;sup&gt;b&lt;/sup&gt;=.74</td>
</tr>
<tr>
<td></td>
<td>Belief</td>
<td></td>
<td>7-point semantic</td>
<td>10 summed/ca = .73</td>
</tr>
<tr>
<td>Study 2/W1</td>
<td>Getting 'A'</td>
<td>Global</td>
<td>Unspecified</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>semantic</td>
<td>4 summed/ca = .69</td>
</tr>
<tr>
<td></td>
<td>Belief</td>
<td></td>
<td>7-point semantic</td>
<td>8 summed/ca = .54</td>
</tr>
<tr>
<td>Study 2/W2</td>
<td>&quot;</td>
<td>Global</td>
<td>Unspecified</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>semantic</td>
<td>5 summed/ca = .79</td>
</tr>
<tr>
<td></td>
<td>Belief</td>
<td></td>
<td>7-point semantic</td>
<td>8 summed/ca = .62</td>
</tr>
<tr>
<td>Beck &amp; Ajzen (1991)</td>
<td>Cheating</td>
<td>Global</td>
<td>7-point semantic</td>
<td>4 summed/ interitem r = .34</td>
</tr>
<tr>
<td></td>
<td>Shoplifting</td>
<td>Global</td>
<td>7-point semantic</td>
<td>4 summed/ interitem r = .48</td>
</tr>
<tr>
<td></td>
<td>Lying</td>
<td>Global</td>
<td>7-point semantic</td>
<td>4 summed/ interitem r = .34</td>
</tr>
</tbody>
</table>

<sup>a</sup> points of scale/type of scale  
<sup>b</sup> coefficient alpha
Table 2
TPB: OTHER MEASURES OF PERCEIVED BEHAVIORAL CONTROL

<table>
<thead>
<tr>
<th>INVESTIGATORS</th>
<th>BEHAVIOR</th>
<th>MEASURE</th>
<th>SCALE&lt;sup&gt;a&lt;/sup&gt;</th>
<th>ITEMS/RELIABILITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Netemeyer &amp; Burton (1990)</td>
<td>Voting</td>
<td>Global</td>
<td>7-point semantic</td>
<td>4 summed/ca&lt;sup&gt;b&lt;/sup&gt; = .86</td>
</tr>
<tr>
<td>Netemeyer et. al. (1991)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study 1</td>
<td>Voting</td>
<td>Global</td>
<td>7-point semantic</td>
<td>4 MVs&lt;sup&gt;c&lt;/sup&gt;/composite&lt;sup&gt;d&lt;/sup&gt; reliability = .76</td>
</tr>
<tr>
<td>Study 2</td>
<td>Weight loss</td>
<td>Global</td>
<td>Unspecified</td>
<td>4 MVs/composite reliability = .84</td>
</tr>
<tr>
<td>DeVellis. et. al. (1990)</td>
<td>Cancer</td>
<td>Global</td>
<td>5-point semantic</td>
<td>1/not applicable</td>
</tr>
<tr>
<td></td>
<td>screening</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beale &amp; Manstead (1990)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interview 1</td>
<td>Limit sugar</td>
<td>Global</td>
<td>7-point semantic</td>
<td>2&lt;sup&gt;e&lt;/sup&gt; summed/ca = .56</td>
</tr>
<tr>
<td>Interview 2</td>
<td>&quot;</td>
<td>Global</td>
<td>7-point semantic</td>
<td>2 summed/ca = .67</td>
</tr>
<tr>
<td>Fishbein &amp; Stasson (1990)</td>
<td>Training</td>
<td>Global</td>
<td>7-point semantic</td>
<td>1/not applicable</td>
</tr>
<tr>
<td></td>
<td>attendance</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hinsz &amp; Nelson (1990)</td>
<td>Faculty turnover</td>
<td>Global</td>
<td>7-point semantic</td>
<td>1/not applicable</td>
</tr>
</tbody>
</table>

<sup>a</sup> - points of scale/type of scale  
<sup>b</sup> - coefficient alpha  
<sup>c</sup> - measured variables in LISREL measurement model  
<sup>d</sup> - composite reliability is analogous to coefficient alpha (Fornell and Larker, 1981)  
<sup>e</sup> - 3 items summed ---> ca = .40 & .56 in Interviews 1 & 2, repectively
(Ajzen and Madden, 1986; Netemeyer and Burton, 1990) provide mixed results of their measures' internal consistency. Further discussion of the measures and their predictive validity is provided in following sections.

Lastly, some investigators have attempted to examine the impact of perceived behavioral control on intentions and behavior by incorporating a modified-PBC measure in the Theory of Planned Behavior or a modified-TPB model. For example, Ronis and Kaiser (1989, p. 1069) interpreted perceived behavioral control as "confidence in one's ability to carry out the action". This study used three "confidence" items as predictors in a model combining components of the TPB and the Health Belief Model (Becker et. al., 1977). In a study in which the TPB was combined with elements of the Protection Motivation Theory, Steffen (1990) constructed a measure with seven "perceived control" - relevant beliefs but obtained these beliefs from measurement scales of the study's other constructs. Finally, Brubaker and Fowler (1990) offered a revised version of the TRA, not unlike the Theory of Planned Behavior, in which a one-item measure of "self-efficacy" was obtained.

In summary, Ajzen and his colleagues have consistently maintained that a set of "control beliefs", defined as beliefs about the availability of requisite resources and opportunities, provide the basis for, or underlie, an individual's perception of control over a given behavior. This set of beliefs is analogous to the set of behavioral and normative beliefs underlying attitude and subjective norm, respectively. Unlike attitude and subjective norm, however, research published to date have not further defined or conceptualized the antecedent of perceived behavioral control. For the most part, empirical studies of the Theory of Planned Behavior have employed direct measures of attitude, subjective norm, and perceived
behavioral control and thus, provide no clear picture of PBC's antecedent. Although the two studies conducted by Ajzen and Madden (1986) included belief-based measures of all three constructs, the belief-based measure of perceived behavioral control differed considerably from the belief-based measures of attitude and subjective norms. Research published to date, therefore, has provided limited information regarding the conceptualization of PBC's antecedent.

**Conceptual distinction from past behavior.** The issue of past behavior's role as it pertained to the Theory of Reasoned Action was addressed in an earlier section. This issue is also relevant in discussing the Theory of Planned Behavior. As previously noted, it has been proposed that an individual's perception of his or her control over a given behavior is likely to reflect, in part, past performance of the target behavior (Ajzen, 1985; Ajzen and Madden, 1986). This proposition is reasonable since prior experience with the behavior of interest would likely provide the individual with information about his or her skills, abilities, sense of willpower, locus of control, need to rely on others' cooperation, etc. Although past behavior may not identify all internal and external factors which might influence successful performance of the target behavior, it most likely contributes to an individual more accurately assessing his control over the behavior. Hence, past behavior's impact on perceived behavioral control is not only theoretically feasible, but probable.

The assumption that the above relationship exists between past behavior and perceived behavioral control does not necessarily imply, however, that the two factors overlap conceptually. As in the case of subjective norm and attitude with respect to a given behavior, PBC may mediate the effects of past behavior without conceptual overlap. Nevertheless, research with the TRA has provided some
support for past behavior's direct effect on behavior that is independent of any effect mediated by subjective norms and attitudes. Therefore, it is reasonable to suggest that past behavior may directly effect behavior in the Theory of Planned Behavior independent of its indirect effect on behavior via attitudes, subjective norms, and perceived behavioral control.

The issue of past behavior has also been addressed by Ajzen and his colleagues in their studies of the Theory of Planned Behavior. In the early stage of the theory's development, Ajzen (1985) suggested that past performance of a behavior may be correlated with control over the behavior in that frequent past behavior, such as excessive drinking or drug use, may reflect an individual's lack of control (i.e. involitional behavior). As a result of its correlation with control, Ajzen hypothesized that past behavior may influence present behavior when it is not entirely volitional. That is, the effect of past behavior on future behavior is mediated through this "control" construct.

In an empirical investigation, Ajzen and Madden (1986) incorporated a measure of past behavior in two studies. This step was taken (p. 460) "to rule out the possibility that the effect of perceived behavioral control is 'nothing but' a self-prediction of future behavior based on past experience". For each study, a hierarchical regression analysis in which past behavior was entered in the equation prior to all other independent variables showed that PBC had a significant effect on intentions above and beyond any effect of past behavior. Whether or not past behavior had a significant effect on intention above and beyond the effect of perceived behavioral control, however, was either not conducted or not reported but would be of interest. Another valuable analysis to conduct would have been to determine past behavior's effect on behavior rather than intention.
Beck and Ajzen (1991) also examined the role of past behavior in the Theory of Planned Behavior. Students were asked to report the frequency of performing three dishonest behaviors (cheating, shoplifting, and lying) in the 12 months prior to the study. In a hierarchical regression in which intention was the dependent variable, past behavior was added to the equation after all predictor variables of interest (attitudes, subjective norms, perceived behavioral control, and perceived moral obligation) were entered. The data analysis indicated that past behavior did attain a significant regression coefficient but added minimum improvement (3% - 5%) in the prediction of the three behaviors. Although one hypothesis offered by the authors for explaining this minimal improvement was that their measure of past behavior was biased downward because of the measure's self-report format, relatively high frequencies reported for cheating (66%), shoplifting (39%), and lying (57%) suggest that students were not unduly influenced by social desirability.

Finally, Bagozzi and Warshaw (1990) examined the role of past behavior in their "Theory of Goal Pursuit", an intention model relatively similar to the Theory of Planned Behavior that replaces intentions with "intention to try", attitude toward the behavior with "attitude toward trying", etc. According to these authors (p. 127), "the meaning of PBC is very close to the meaning of expectation of success and failure that are included" in their TGP model. In their study of students' weight loss, Bagozzi and Warshaw proposed that the 'frequency' of past 'trying behavior' would influence the 'intention to try'. The authors based the F --> BI pathway on the premise that attitudes may be only partially self-generated inferences rather than perfect reflections of 'past trying behavior', and thus, may independently impact 'intention to try'. 'Recency' of 'past trying behavior' was proposed to influence 'trying behavior' to the extent that actual 'trying behavior' differed from the biased
'intention to try'. The 'intention to try' was proposed to be biased due to recency heuristics that would affect all of the determinants of 'intention'. Study results supported the authors' hypotheses, leading them to recommend including both characteristics of past behavior in the behavioral intention model and expecting a high correlation between them. However, Bagozzi and Warshaw did not test for any possible effect of the 'recency' of 'past trying behavior' on 'intention'. Nevertheless, if the TGP is accepted as a relatively close representation of the Theory of Planned Behavior, the role of past behavior in a behavioral intention model has some support.

The two studies conducted by Ajzen and his colleagues (Ajzen and Madden, 1986; Beck and Ajzen, 1991) in addition to the Bagozzi and Warshaw's (1990) findings provide somewhat mixed results regarding the role of past behavior in the Theory of Planned Behavior. Ajzen and Madden's study suggests that past behavior has no valid role in the model because PBC's impact on intention was significant and went beyond any effect of past behavior. However, the study did not report if past behavior had an effect on intention above and beyond that of PBC. Furthermore, no results were reported pertaining to past behavior's effect on behavior. On the other hand, Beck and Ajzen (1991) found that past behavior did directly affect behavioral intentions. In addition, the role of past behavior on intention and behavior found support in the study conducted by Bagozzi and Warshaw (1990). These results suggest that the TPB's overall causal structure may yet lack the variables to sufficiently predict human behavior. The question of past behavior's role in the Theory of Planned Behavior is addressed by Ajzen and his colleague in the context of a model's "sufficiency".
According to Beck and Ajzen (1991), past behavior can be used to test a model's sufficiency. In short, a sufficient model is defined as one that contains all the factors in the set of determinants and thus, accounts for all non-error variance in the behavior. If a model is sufficient, it should not significantly improve the prediction of behavior when past behavior is added. If, however, the addition of past behavior has a significant residual effect beyond the effect of the predictor variables included in the model, it suggests that all the factors determining the behavior have not been identified. Beck and Ajzen note one reservation to the situation described above, i.e. not all factors are identified: the measures of past and later behavior share common error variance that is not shared by measures of the other model variables. In summary, then, Beck and Ajzen attribute past behavior's potential residual effects in predicting behavior to: (1) common error variance shared in the measures of behavior or (2) factors that should be included in the set of determinants to ensure the model's sufficiency.

Many studies attempting to predict specific behaviors with the TRA or the TPB have either directly or indirectly challenged these models' sufficiency by proposing additional variables that might improve the models' predictive utility. In fact, such challenges to the TRA finally led to the incorporation of perceived behavioral control and the origination of the Theory of Planned Behavior. Including additional variables in this model to test its sufficiency in predicting human behavior, then, is anticipated.

**PBC's current conceptualization and conceptual issues: summary remarks.** The review of the conceptual process of the perceived behavioral control construct has raised several issues. First, some researchers have felt that the conceptualization of
this construct, particularly in its early stage, led to confusion about its role in a model for explaining and predicting human behavior. Ajzen, however, has been relatively consistent in describing the construct as most similar to Bandura's (1977, 1982) concept of self-efficacy beliefs. According to Ajzen (1991, in press), the Theory of Planned Behavior is able to place the concept of "self-efficacy belief" or "perceived behavioral control" in a general framework of the relationships among beliefs, attitudes, intentions, and behavior. The advantage of this approach is that the model in which PBC has been placed (i.e., TRA) has already received considerable empirical support in the literature.

Another issue involves the extent to which PBC's determinants, as conceptualized and proposed by Ajzen in currently published literature, accurately reflect the concept of perceived behavioral control. Ajzen has consistently maintained that a set of beliefs about the availability of requisite resources and opportunities, i.e., "control beliefs", provide the basis for, or underlie, the perceived behavioral control concept. Although this approach toward conceptualizing perceived behavioral control appears to be consistent with the concept of "behavioral" and "normative" beliefs that purportedly underlie attitude and subjective norm, respectively, subtle differences exist. Specifically, behavioral and normative beliefs are viewed in terms of the likelihood that: (1) performing the behavior results in a particular outcome and (2) a particular referent thinks that the individual should or should not perform the behavior, respectively. However, in the case of "control beliefs", Ajzen and Madden (1986) have used both the likelihood and the frequency of the availability of requisite resources and opportunities in their belief-based measures. Therefore, this difference introduces one point at which their
approach for conceptualizing attitude and subjective norm veers from their approach for conceptualizing perceived behavioral control.

Based on the presumed role that behavioral and normative beliefs have in determining attitude and subjective norm, respectively, it is logical to suggest that control beliefs underlie perceived behavioral control. However, the conceptualization of attitude and subjective norm proceed beyond this point whereas perceived behavioral control does not. The proposition that a set of beliefs about an individual's control over a given behavior can adequately encompass the entire concept of perceived behavioral control seems rather simplistic if not, shortsighted. Although elaborate conceptualization of a construct is not prerequisite for its contribution to a model, human behavior is, for the most part, complex. Accordingly, it is not unreasonable to expect that models proposed to sufficiently explain and predict complex human behavior may include components that are complex, rather than simple and straightforward, in nature.

Finally, the role of past behavior and its relationship with perceived behavioral control is an issue to consider. Although this was also a consideration of the TRA, it may be more so with the Theory of Planned Behavior due to the conceptualization and definition of perceived behavioral control. Ajzen and his associates seemingly prefer to address this topic in the realms of discussing a model's sufficiency. Determining the sufficiency of the Theory of Planned Behavior in explaining and predicting human behavior is a difficult undertaking at this time but is addressed in a later section.
TPB: Validity and Reliability Issues

Evaluating the validity and reliability of the Theory of Planned Behavior's overall causal structure and components involves two areas for discussion: (1) indirect and direct support from validation research with the TRA and the TPB, respectively, and (2) validity and reliability issues requiring further attention.

TPB Validity: Indirect and Direct Support

Research assessing the TRA's validity and reliability has been previously reviewed. Since the Theory of Planned Behavior is an extension of the TRA, the validation of the TRA's causal structure and measures lend support to the validity and reliability of the TPB. However, the inclusion of an additional component and more pathways in the Theory of Planned Behavior alters the overall framework of the causal model. Therefore, while validation of the TRA indirectly supports the TPB, blind acceptance of the TPB's validity based solely on the TRA is inappropriate. The following discussion first briefly summarizes the research validating the TRA and its implications for validating the Theory of Planned Behavior. Next, research that has directly examined the validity of the Theory of Planned Behavior is reviewed.

Indirect validation. Previous discussion of the TRA's validity has addressed several issues, including: (1) the construct validity of the determinants of intentions and behavior, (2) the correlation of the belief-based measures with their direct measure counterparts, i.e. the predictive validity of the expectancy-value and normative composites (3) the addition of other variables to improve the prediction of intentions and behavior, i.e. predictive validity of the overall model, and (4)
recommendations by Ajzen and Fishbein (1980, Appendices A & B) for developing reliable and valid measures of the TRA's components. Results of this research addressing these issues imply that the Theory of Planned Behavior possesses validity.

In terms of the construct validity of intention's determinants, the TPB retains the conceptual distinction between the model's attitudinal and normative components. The model's novel component, perceived behavioral control, is also proposed as a separate construct. While there is no reason to expect that the distinction between the attitudinal and normative constructs would not prevail, introducing a new component to the model changes the model's overall causal structure. Therefore, the conceptual distinction and independent impact of PBC, subjective norm and attitude, on intentions and behavior require empirical support.

The second issue involves the predictive validity of the belief-based measures, i.e. the correlation with their directly measured counterparts. Similar to attitudes and subjective norms, the belief-based measure of perceived behavioral control would be expected to correlate more highly with its direct measure than with the direct measures of attitudes or subjective norms. Assurance of predictive validity requires empirical support from studies of the Theory of Planned Behavior. This assurance is difficult to obtain from currently available research because all published studies, excluding Ajzen and Madden's (1986) investigation, have included only the direct PBC measure. Ajzen and Madden reported significant correlations between the belief-based and direct measures of attitude (.47 to .58, p < .01), subjective norm (.47 to .57, p < .01), and perceived behavioral control (.54 to .63, p < .01). However, since no correlations were reported between the belief-based PBC measure and the direct ATT and SN measures, or the belief-based
ATT measure and the direct SN and PBC measure, etc., research supporting the predictive validity of the belief-based PBC measure is somewhat limited.

The third issue addresses the predictive validity of the Theory of Planned Behavior as a whole and any improvement in this model's predictive utility after incorporating additional variables. This issue describes the process by which the validity of the TRA was evaluated and eventually improved via incorporating the perceived behavioral control construct. In terms of the Theory of Planned Behavior, the model's predictive validity is tested in empirical studies that apply the model to predict intentions and behavior. In addition, studies that incorporate other variables to improve prediction of a given behavior are, in fact, testing the model's overall predictive validity.

Finally, the recommendations provided by Ajzen and Fishbein (1980, Appendix B) for valid and reliable measurement of the TRA's components are applicable to the Theory of Planned Behavior. However, scales for the new component, i.e. perceived behavioral control, need evaluated in terms of their validity and reliability.

Direct Validation. Studies have provided some direct support for the Theory of Planned Behavior's validity and reliability. This review discusses empirical support for the belief-based measures' predictive validity, the construct validity of the determinants of intentions and behavior, and steps taken by Ajzen and his colleagues for developing reliable and valid measures of the TPB's components. The predictive validity of the overall model, however, is discussed in the section pertaining to applications of the Theory of Planned Behavior and accompanying research concerns.
In terms of the predictive validity of belief-based measures in applications of the Theory of Planned Behavior, Fishbein and Stasson (1990) reported that the belief-based measures had relatively high correlations of .51 and .67 with the corresponding direct measures of attitude and subjective norm, respectively. Although these findings support previous research with the TRA, the study did not include a belief-based PBC measure and thus, does not provide support of predictive validity for this construct. However, low correlations were reported between the direct PBC measure and: attitude (r = .07), subjective norms (r = .01), belief-based attitude (r = -.15), and belief-based subjective norm (r = -.10). Although these findings seem to suggest that perceived behavioral control is a construct that is independent from attitudes and subjective norms, it was not a significant predictor of intentions or behavior. Therefore, rather than indicating an independent construct, the study’s results are more indicative of a poorly measured construct.

The study conducted by Ajzen and Madden (1986) did provide evidence of predictive validity for belief-based PBC, attitude, and subjective norm measures. In a study of two behaviors of college students, the correlations between the belief-based measures and their direct measures were for Study 1, Study 2/wave 1 and Study 2/wave 2, respectively: .51, .47, and .58 for attitude; .47, .57, and .51 for subjective norm, and .54, .55, and .63 for perceived behavioral control. The magnitude of these correlations suggests that the belief-based measures are relatively predictive of the constructs they purportedly measure. Since the correlations between measures of attitude, subjective norm, and perceived behavioral control were not reported, support for these components’ discriminant validity is rather limited.
The majority of studies based on Ajzen and his colleague's (Schifter and Ajzen, 1985; Ajzen and Madden, 1986) early work minimally address reliability and validity issues pertaining to the Theory of Planned Behavior and its components. However, one study does merit attention. Netemeyer et. al. (1991) used structural equation modeling to examine the Theory of Planned Behavior in predicting two behaviors of differing volitional status: (1) voting as an example of a behavior with a high degree of individual control (Study 1), and (2) weight loss as an example of a behavior under much less individual control (Study 2). A major advantage of this study is that it was the first and only study, to the best of this investigator's knowledge, that examined and compared the TRA and the TPB with confirmatory factor analysis. This statistical approach is unique in that it not only provides a more rigorous test of theoretical specifications in the TRA and TPB but it also provides a more rigorous assessment of the validity and reliability of models and their components.

In terms of evidence for the construct validity of components and their measures generated by Netemeyer et. al.'s study (1991), composite reliabilities, which are purportedly analogous to coefficient alpha (Fornell and Larcker, 1981), ranged from .735 to .915 in Study 1 and .835 to .910 in Study 2. Thus, these indices suggest that adequate internal consistency was achieved in developing study measures. The authors also reported another indicator of construct representation, i.e. "variance-extracted estimates". This indicator represents the amount of variance captured by a construct in relation to the random measurement error. According to study results, all but one estimate (PBC, Study 1) met Fornell and Larker's "acceptable level" of .50 or over thus, suggesting that the constructs were reasonably well specified. Although other indications of construct validity are obtainable or generated in a
structural equation analysis (e.g. measures of one construct "loading" on another), Netemeyer et. al. do not report any problems with their measurement models nor make specific references to the validity of either the TRA or the Theory of Planned Behavior. Further discussion of this study's contribution to TPB's overall predictive validity is addressed in a following section.

The final topic regarding direct support for the TPB's validity and reliability is the availability of any standardized or tested format for valid and reliable measurement of the model's components. As previous described, Fishbein and Ajzen (1980, Appendices A and B) have recommended: (1) elicitation exercises to identify salient behavioral beliefs and normative referents, and (2) questionnaire and measurement scale formats for the attitude, subjective norm, behavioral intention, and behavior components of the TRA. Ajzen (1985; 1986; 1988; 1991) has yet to formally recommend specific procedures for developing a valid and reliable belief-based or direct measure of perceived behavioral control. However, the investigation conducted by Ajzen and Madden (1986) provides some guidelines for developing measures.

Similar to the currently recommended procedure for developing valid and reliable measures for the TRA's components, Ajzen and Madden (1986) conducted pilot projects involving elicitation exercises to identify salient factors that could facilitate or inhibit the behaviors under study in order to develop belief-based PBC measures. Contrary to the recommendations for developing measures of attitudes, subjective norms, and their antecedents, however, both belief-based and direct PBC measures developed in Ajzen and his colleagues' studies (Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Beck and Ajzen, 1991) were less standardized in that: (1) the scales for direct PBC measures varied between studies, in terms of type (e.g.
semantic differential versus a likelihood scale ranging from 0 to 100), (2) the anchors for scales of direct PBC measures varied between studies, in terms of both the extent of bipolarity (e.g. extremely likely/extremely unlikely, complete control/very little control) and the adjective pairs used (e.g. true/false, easy/difficult), and (3) the anchors for the scales of belief-based PBC measures varied depending on the nature of the facilitating or inhibiting factor (e.g. never/frequently, many events/none at all. Since other investigators testing the TPB or including a "PBC" component in their modified-TRA model have used a direct PBC measure very similar, if not identical, to Ajzen and his colleagues' measures, it appears that this approach is perceived, at this point, as the "standardized" format for developing PBC measures.

In summary, research has provided some support, both direct and indirect of the predictive and construct validity of the Theory of Planned Behavior's components. However, only one study, to date, has included a belief-based measure of perceived behavioral control and thus, minimal knowledge is available on the predictive validity of PBC's determinant as proposed by Ajzen and his colleagues. Other issues regarding validity and reliability are important to discuss. The predictive validity of the model overall is addressed in a following section. The issue of constructs' dimensionality is discussed next.

Validity and Reliability Issues

Other issues pertaining to the validity and reliability of the Theory of Planned Behavior must be addressed. For example, determining a construct's dimensionality before developing an instrument to measure it is a validity concern. Minimal
attention to the issue of unidimensionality, however, continues with studies testing the Theory of Planned Behavior.

As previously reviewed, research with the Theory of Reasoned Action has supported the multidimensional nature of both expectancy-value attitude and the normative belief-motivation to comply composite. However, in the Theory of Planned Behavior, Ajzen (1985; 1987; 1988) continues to conceptualize these constructs as unidimensional in structure. This issue has been recently addressed by Ajzen and Madden (1986, p.461):

"{The belief-based attitude} measure is derived from expectancy-value theory which assumes that attitude is a function of all salient beliefs about the attitude object. Consequently, no attempt was made to refine this measure by means of item analysis or to assure its unidimensionality by means of confirmatory factor analysis. For the same reason, all belief items were retained in the belief-based measures of subjective norm and perceived control, described below."

Therefore, based on expectancy-value theory, Ajzen and his colleagues do not support multidimensional representations of expectancy-value attitude, the normative belief-motivation to comply composite, or the determinant(s) of perceived behavioral control.

Ajzen and Madden (1986) did address the dimensionality of their direct measures of perceived behavioral control. In reporting the results from confirmatory factor analyses, they maintained that their direct PBC and BI measures represented unidimensional scales in Experiments 1 and 2. In addition, eight- and ten-item belief-based attitude (i.e. expectancy-value) measures were developed after confirmatory factor analyses identified a subset of bipolar adjectives that represented one evaluative dimension for each studied behavior. Therefore, while the authors addressed the dimensionality of the direct measures, the unidimensionality of the
belief-based measures were either assumed or the measures were developed from one evaluative dimension. The relatively unimpressive alpha coefficients of the belief-based measures reported earlier (see Table 1, p. 77) may be due, in part, to this assumption, rather than establishment, of unidimensionality.

The multidimensional representation of expectancy-value attitude is suggested by DeVellis et. al.'s (1990) study of the TPB in predicting cancer screening participation. The authors conducted a principal components analysis (oblique rotation) in which 10 of 13 belief-evaluation products loaded (ranging from .56 to .76) on two factors explaining 30% of the total item variance. The items loading on the two factors pertained to "efficacy" and "barriers" with respect to the behavior under study. The characterization of these two factors seems relatively similar to Ajzen's description of "control factors", i.e. the resources and opportunities that impede or facilitate an individual's behavioral performance. The dimensionality of the NBMC composite was not addressed in this study, perhaps because only three normative referents were included for measurement. In addition, since the global perception of behavioral control was measured with only one direct item, determining the dimensionality of either a belief-based or direct measure of the construct was not an option in this study.

In summary, research with the Theory of Planned Behavior has examined the structure underlying the perceived behavioral control construct. Although Ajzen and his associates tested the unidimensional nature of direct PBC measures, their allegiance with expectancy-value theory denies any consideration of belief-based PBC measures as multidimensional in structure. If, however, researchers demonstrate that belief-based measures of perceived behavioral control are, in fact, multidimensional, arguments by Bagozzi (1982; 1983) that were discussed earlier
would also hold for this construct. That is, if the assumption of PBC's unidimensionality is violated, invalid predictions of intentions and behavior can occur.

**TPB: Application and Research Concerns**

Since its introduction, the Theory of Planned Behavior has been tested by several investigators in a variety of behavioral settings. Other investigators report testing modified versions of either the Theory of Planned Behavior or the perceived behavioral control construct. In general, results have provided mixed support for the theory. This section first reviews empirical investigations that have evaluated the theoretical structure of the Theory of Planned Behavior as well as the role of perceived behavioral control in the model. Next, factors that offer potential explanation for the mixed empirical support are discussed. Finally, concluding remarks pertaining to the theory are provided.

**Empirical Study: TPB and Perceived Behavioral Control**

Empirical study of the Theory of Planned Behavior and the role of perceived behavioral control has been conducted by Ajzen and his colleagues as well as other investigators. Some of the results presented in this section have been briefly discussed in a previous section but warrant further attention. The research conducted by Ajzen and his colleagues is first discussed. Next, a review of other investigators' research is provided. The two sources of empirical evidence are considered separately because the research of Ajzen and his colleagues has provided the basis for the research conducted by others.
Research by Ajzen and colleagues. Generally speaking, research conducted by Ajzen and his associates has provided positive support for the Theory of Planned Behavior. This discussion addresses three empirical investigations of Ajzen and his colleagues that examined six behaviors of college students: weight loss, class attendance, obtaining an 'A' in a specified class, cheating on exams, shoplifting, and lying to get out of assignments.

In a study of college women's weight loss behavior, Schifter and Ajzen (1985) found that PBC, SN, and ATT were all significant predictors of women's intention to lose weight over a six week period. Specifically, adding PBC to the Theory of Reasoned Action increased the amount of variance explained in BI from 42% to 55%. In terms of predicting actual weight loss (B), intentions alone accounted for 6% of the variance. When PBC was added to the model, however, 19% of the variance in B was explained. Furthermore, a marginally significant interaction between BI and PBC (p < .10) increased the amount of explained variance in B to 22%. Therefore, Schifter and Ajzen's study supported both PBC→BI and PBC→B pathways as well as a marginally significant interaction between PBC and BI. However, the model as specified by the Theory of Planned Behavior was unable to account for a substantial amount (81%) of unexplained variance in weight loss behavior.

The second investigation is one conducted by Ajzen and Madden (1986) in which two behaviors of college students were studied: attendance of class lectures (Study 1) and obtaining an 'A' in a specific course (Study 2). In the first study, a hierarchical regression analysis indicated that when the TRA was used to predict students' intentions to attend class, both ATT and SN were significant predictors, accounting for 30% of the variance in BI. When students' perception of their
control over attending class (PBC) was added to the regression equation, it also became a significant predictor of BI and the amount of explained variance in BI increased significantly to 46% \( (p < .01) \). In terms of predicting students' attending class (B), their intentions accounted for 13.0% of the variance and the addition of PBC did not increase the amount of explained variance in B (13.7%). The presence of an interaction effect was not found in the prediction of either students' intentions or behaviors. Therefore, in Study 1, Ajzen and Madden found support for a PBC--->BI pathway but no support for a PBC--->B pathway and interactive effects. Ajzen and Madden attribute the absence of the PBC--->B pathway to the highly volitional nature of the studied behavior.

Ajzen and Madden's (1986) second study consisted of two waves. A questionnaire was administered three weeks into the spring semester (Wave 1) to a group of undergraduate students and then readministered approximately one week prior to the final examination period (Wave 2). Again, two hierarchical regression analyses were performed with first BI and then B as the dependent variables. In using the TRA to predict students' intentions (BI) to obtain an 'A' in a specified class, the student's attitude was the only significant predictor for both Waves 1 and 2. The addition of students' perception of their control over getting an 'A' (PBC) to the regression equation significantly improved the amount of explained variance in BI from 23% to 42% in Wave 1 and from 24% to 41% in Wave 2 \( (p < .01) \). In this model, i.e. the Theory of Planned Behavior, students' ATT and PBC were significant predictors of BI \( (p < .01) \). Subjective norm, however, was not a significant predictor of BI with PBC either in or out of the model.

The regression analyses in which B was the dependent variable provided different results for Waves 1 and 2. Specifically, when PBC was added to the
regression equation in Wave 1, the regression coefficient of BI was significant \((p < .01)\) but the coefficient of PBC was not significant. In fact, the addition of PBC explained no more variance in behavior \((6.7\%)\) than was already explained by intentions. On the other hand, when PBC was added to the regression equation in Wave 2, both PBC and BI attained statistically significant regression coefficients \((p < .01)\) and the amount of explained variance in B significantly increased from 15\% to 20\% \((p < .01)\). The second study, therefore, supported the PBC\(\rightarrow\)BI pathway in both waves but only supported the PBC\(\rightarrow\)B pathway in Wave 2. Ajzen and Madden (1986) suggest that the difference between the two waves resulted from the passage of time in which students gained feedback about their class performance and hence, were better able to evaluate their actual control over getting an 'A' in the course.

The third and final investigation to be discussed in this section is a study of three 'dishonest' student behaviors: cheating on exams, shoplifting, and lying to get out of assignments. Beck and Ajzen (1991) found that when PBC was added to ATT and SN in the regression equation, the amount of explained variance in students' intention significantly increased from 45\% to 67\% for cheating, 61\% to 69\% for shoplifting, and 32\% to 62\% for lying \((p < .05)\). In fact, of the three predictors of BI, perceived behavioral control was the only one that attained a significant regression coefficient across the three behaviors. On the other hand, when B was the dependent variable and both BI and PBC were entered simultaneously in the regression equation, BI achieved a significant regression coefficient for all three dishonest behaviors but the coefficient for PBC was not significant for any of them. Results of Beck and Ajzen's (1991) study, then, support the PBC\(\rightarrow\)BI pathway for all three dishonest behaviors. However, support for the PBC\(\rightarrow\)B pathway was
not found. Also, the study failed to support any two-way (i.e. PBC x BI) or three-way (i.e. ATT x SN x PBC) interactions.

Beck and Ajzen (1991) admit that while the Theory of Planned Behavior was able to predict intentions quite accurately for the three dishonest behaviors they studied, the model met difficulties in predicting self-reported behaviors. As mention, the first step of the hierarchical regression analyses for behavior included both intention and perceived behavioral control. The second and third step added other variables of interest, i.e. moral obligation and past behavior, respectively. The inclusion of both BI and PBC in the first step, therefore, does not provide a means to calculate the amount of variance explained solely by either BI or PBC. The authors do report, however, that the TPB model was unable to account for 45%, 77%, and 88% of the variance in students' cheating, shoplifting, and lying behaviors, respectively. The investigators attribute this relative lack of success to students lacking the experience and insight regarding their motivations and capabilities with respect to these behaviors. They suggest that students' intentions and perceived behavioral control did not accurately reflect their true dispositions and thus, did not permit them to accurately predict their later behavior. Another explanation of the unsuccessful prediction of the three dishonest behaviors is possible measurement bias introduced by the use of self-reports for this type of behavior. This issue has been previously discussed and as claimed by the authors, the relatively high frequencies reported by the students for the three "dishonest" behaviors suggest that students were not influenced by social desirability.

In summary, Ajzen and his colleagues have consistently documented the effect perceived behavioral control has on the motivational determinant of behavior, namely, intentions. This pathway, PBC→BI, was found to be significant for all
six behaviors under study. The direct effect of perceived behavioral control on behavior, however, has received much less support. Specifically, the PBC→B pathway was found in only two of the six studied behavioral settings (weight loss and obtaining an 'A', Wave 2). Lastly, minimal support was found for any interactive effects in that no support was found for PBC interacting with ATT and SN but one study (weight loss) found a marginal interactive effect between PBC and BI (P < .10). A summary of the six studied behaviors conducted by Ajzen and his colleagues is provided in Table 3.

Research by other investigators. Mixed support for the Theory of Planned Behavior and the role of perceived behavioral control in the model has been provided by other investigators' research. The indirect effect of perceived behavioral control on behaviors, i.e. the PBC→BI pathway, has been largely supported. However, evidence of perceived behavioral control's direct effect on behavior, i.e. the PBC→B pathway, has been limited to date.

The following discussion first addresses four investigations positively supporting the PBC→BI pathway: (1) students' voting (Netemeyer and Burton, 1990); (2) students' voting and weight loss (Netemeyer et. al., 1991); (3) cancer screening participation (DeVellis et. al., 1990); and (4) mothers' limiting the frequency if their infants' sugar intake (Beale and Manstead, 1991). Next, two investigations that have been unable to support the PBC→BI pathway are reviewed: (1) employees' training session attendance (Fishbein and Stasson, 1990), and (2) university faculty turnover intentions (Hinsz and Nelson, 1990). Finally, studies that have examined modified-TRA models or models combined with other behavioral theories are briefly addressed.
Table 3
TPB: FINDINGS OF EMPIRICAL STUDIES BY AJZEN & COLLEAGUES

<table>
<thead>
<tr>
<th>INVESTIGATORS</th>
<th>BEHAVIOR</th>
<th>SUPPORT PBC→BI</th>
<th>BI:UNEXP&lt;sup&gt;a&lt;/sup&gt; VARIANCE</th>
<th>SUPPORT PBC→B</th>
<th>B:UNEXP VARIANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schifter &amp; Ajzen (1985)</td>
<td>Weight loss</td>
<td>Yes</td>
<td>45%</td>
<td>Yes&lt;sup&gt;b&lt;/sup&gt;</td>
<td>81%</td>
</tr>
<tr>
<td>Ajzen &amp; Madden (1986)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study 1</td>
<td>Attending class</td>
<td>Yes</td>
<td>54%</td>
<td>No</td>
<td>86%</td>
</tr>
<tr>
<td>Study 2/W1</td>
<td>Getting 'A'</td>
<td>Yes</td>
<td>58%</td>
<td>No</td>
<td>93%</td>
</tr>
<tr>
<td>Study 2/W2</td>
<td>&quot;</td>
<td>Yes</td>
<td>59%</td>
<td>Yes</td>
<td>80%</td>
</tr>
<tr>
<td>Beck &amp; Ajzen (1991)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cheating</td>
<td>Yes</td>
<td>33%</td>
<td>No</td>
<td>45%</td>
<td></td>
</tr>
<tr>
<td>Shoplifting</td>
<td>Yes</td>
<td>31%</td>
<td>No</td>
<td>77%</td>
<td></td>
</tr>
<tr>
<td>Lying</td>
<td>Yes</td>
<td>38%</td>
<td>No</td>
<td>88%</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup> - Unexplained variance
<sup>b</sup> - Also found marginal PBC x BI interaction (p < .10)
Netemeyer and Burton (1990) tested students' voting intentions and behavior in comparing both the TRA with the TPB and a behavioral expectation (BE) measure with a behavioral intention (BI) measure. Hence, two sets of hierarchical regression analyses were performed: (1) one in which BI was the dependent variable followed by B as the dependent variable, and (2) one in which BE was the dependent variable followed by B as the dependent variable. The analyses in which either BI or BE was the dependent variable are first addressed followed by a discussion of the analyses in which B was the dependent variable (i.e. regressed onto BI or BE).

The regression analysis in which BI was regressed onto ATT and SN, both predictors were significant. Adding students' perception of control over their voting (PBC) to the regression equation resulted in significant coefficients for ATT and PBC; however, the coefficient for SN became insignificant. Furthermore, the addition of PBC to the Theory of Reasoned Action significantly increased the amount of variance explained in students' intention to vote from 20% to 65% (p < .01). The regression analysis in which BE served as the predicted variable provided results similar to those found with behavioral intention. That is, when PBC was added to the regression equation with SN and ATT, the amount of explained variance increased significantly from 8% to 29% (p < .01). Therefore, in both cases (i.e. BI or BE as the dependent variable), PBC was a significant predictor.

The hierarchical regression in which students' self-reported voting behavior (B) was regressed onto intentions followed by adding PBC to the regression equation provided results different than those described above. Specifically, the addition of PBC did not improve the 35% of variance explained in B by BI. However, when B was regressed onto BE and then PBC was added to the regression equation, the amount of variance explained in students' voting behavior increased significantly
from 15% to 27% (p < .01). In addition, Netemeyer and Burton found no interaction effects in any of the regression analyses conducted.

Netemeyer and Burton (1990) found support, then, for the PBC—>BI and PBC—>BE pathways. No support for the PBC—>B pathway was found when BI was the mediating variable; however, the PBC—>B pathway was supported when BE replaced intentions as the mediating variable. While this finding may at first suggest that BE is more appropriate than BI as an antecedent of behavior in the TPB, other study results must be considered, including: (1) the ATT and SN measures were more strongly correlated with BI (20% variance explained) than they were with BE (8% variance explained), (2) after adding PBC to ATT and SN, the three measures were more strongly correlated with BI (65% variance explained) than they were with BE (29% variance explained), (3) BI more strongly predicted B (35% variance explained) than BE predicted B (15% variance explained), and (4) BI and PBC together predicted B more strongly (35% variance explained) than BE and PBC together predicted B (27% variance explained). Therefore, Netemeyer and Burton maintain that for the behavior studied, intention was the stronger antecedent of behavior in both the TRA and the TPB. The authors attribute the absence of the PBC—>B pathway in their study to the highly volitional nature of students' voting behavior. They conclude that in a study of similar behavior, perceived behavioral control would indirectly affect behavior via intentions but would not directly influence behavior.

Another study conducted by Netemeyer et. al. (1991) tested the Theory of Planned Behavior with two behaviors that they believed to vary in the extent to which they are under a student's volitional control: voting (high degree of volitional control) and weight loss (low degree of volitional control). The TRA was compared
to two versions of the Theory of Planned Behavior: TPB-1 which included the PBC→BI pathway but not the PBC→B pathway and TPB-2 which included both the PBC→BI and the PBC→B pathways.

Supported by earlier research (Netemeyer and Burton, 1990), Netemeyer et. al. (1991) proposed that the TPB-1 offered the most parsimonious model for predicting students' voting. The second version, TPB-2 was proposed to be the most parsimonious model for predicting weight loss. Both versions of the Theory of Planned Behavior, as well as the TRA, were tested for both behaviors under study.

In terms of comparing the models' ability to predict students' voting behavior, Netemeyer et. al. (1991) apparently used the same data analyzed in Netemeyer and Burton (1990). However, the data in the earlier study was analyzed by hierarchical regression analyses whereas Netemeyer et. al. (1991) used structural equation modeling for this study's data analysis. Study results indicated that TPB-1 (without PBC→B) fit the data significantly better than the TRA (p < .01) and increased the amount of explained variance in BI by 26%. However, the addition of the PBC→B pathway (i.e. TPB-2) did not provide a significant increase in fit and the accompanying increase in variance explained in behavior was only .2%.

The study of weight loss behavior by Netemeyer et. al. (1991) found that TPB-1 fit the data significantly better than the TRA (p < .01) and significantly increased the amount of explained variance in intentions by 36%. Furthermore, adding the PBC→B pathway (TPB-2) significantly improved the model’s fit to the weight loss data (p < .05) and significantly increased the amount of explained variance in intentions by 3.7%.

In summary, Netemeyer et. al.'s (1991) research supports perceived behavioral control's indirect effect on behavior (i.e. PBC→BI) for any behavior that is
involitional to some extent. However, the authors propose that the direct effect of PBC on behavior (i.e. PBC ---> B) will only emerge when the behavior of question is under a low degree of volitional control. That is, behaviors that are relatively involitional in nature, are better predicted with the Theory of Planned Behavior in which both direct and indirect pathways originating from perceived behavioral control are incorporated.

DeVellis et. al. (1990) tested the Theory of Planned Behavior in predicting individuals' participation in colorectal cancer screening. Two groups of individuals participated in the study: (1) those recently informed that they were at a "high-risk" for developing this type of cancer and (2) those that were not at a "high-risk" but rather considered "average-risk" individuals. The authors predicted that the behavior was unlikely to be under complete volitional control and thus, perceived behavioral control would add significantly to the prediction of individuals' screening behavior, over and above the effects of attitudes and subjective norms.

Results from DeVellis et. al.'s (1990) study supported a significant PBC effect on both BI and B (i.e. PBC ---> BI and PBC ---> B pathways) for "high-risk" individuals. However, only a significant PBC ---> BI pathway was found for "average-risk" individuals. Specifically, the addition of PBC increased the amount of explained variance in BI from 13% to 21% (p < .01) and from 22% to 29% (p < .001) for the "high-risk" and the "average-risk" groups, respectively. In terms of predicting B, hierarchical regression analyses in which PBC, SN, and ATT were entered in the first step and BI was entered in the second step, showed that PBC retained a significant regression coefficient after the second step for the "high-risk" group (p < .01). However, the regression coefficients for PBC were not significant after the first and second steps for the "average-risk" group. The authors explained
that they included SN and ATT in the regression analysis' first step as control variables because similar to SN and ATT, if the effect of PBC became insignificant when behavioral intention was added to the model, the mediational role of BI would be supported. The approach undertaken in this study's hierarchical regression analysis, however, does not allow one to calculate any change in variance explained in behavior due solely to direct effect of perceived behavioral control.

DeVellis et. al. (1990) also report finding a three-way interaction among perceived behavioral control, knowledge, and intention in the prediction of behavior for the "high-risk" group. The authors suggest that inconsistencies found between their results and those predicted by the Theory of Planned Behavior may be attributed, in part, to unstable attitudes, perceptions of behavioral control, intentions, etc. in "high-risk" individuals who learned of their "risk status" one week prior to the study.

The final investigation to be discussed in this section that supported the PBC---> B pathway is one conducted by Beale and Manstead (1991). This study examined mothers' intentions to limit the frequency of sugar intake by their infants. The behavior under study was characterized as a health-related behavior because limiting the frequency of infants' sugar intake can decrease dental decay. Therefore, given the nature of this behavior, the authors hypothesized that the behavior may not be entirely volitional in nature and that perceived behavioral control would significantly add to the prediction of intentions, over and above the effect from subjective norms and attitudes. Although this study included an experimental component, its test of the Theory of Planned Behavior was conducted with the entire sample (i.e. experimental and control groups) for two time periods: (1) the first interview, and (2) the second interview.
Beale and Manstead (1991) performed two hierarchical regression analyses (Interview 1, Interview 2) in which intention was the dependent variable and found that the TRA's components accounted for 11% and 21% of the variance at the first and second interviews, respectively. When PBC was added to the regression equation, it had a significant regression coefficient at both the first and second interviews (p < .01). Furthermore, the addition of PBC significantly increased the amount of explained variance in mothers' intentions to 16% and 27% at Interview 1 and Interview 2, respectively (p < .01).

Beale and Manstead's (1991) investigation, therefore, supports the PBC → BI pathway and the Theory of Planned Behavior. However, two limitations to the study are important to address. First, as noted by the authors, the amount of unexplained variance in mothers' intentions to limit the frequency of infants' sugar intake was quite high, ranging from 73% to 84%. Beale and Manstead attribute this to the nature of the studied behavior. Specifically, they suggest that limiting the frequency of infants' sugar intake is not a behavior generally recognized as an effective means to combat tooth decay. They (p. 427) propose that "[this type of behavior], therefore, hardly merits the descriptions 'reasoned action' or 'planned behavior' and it is not altogether surprising that measures of ATT, SN, and PBC accounted for relatively little of the variance in intentions". The study's second limitation is its investigation of intentions only. Since behavior was not measured, neither positive nor negative evidence of the PBC → BI pathway could be attained.

One of the two studies not finding support of the PBC → BI pathway was conducted by Fishbein and Stasson (1990). This study tested the Theory of Planned Behavior in predicting employees' attendance at a training session. Similar to Netemeyer and Burton (1990), the authors attempted to differentiate between
behavioral intention and behavioral expectation by including measures of both. Intention or motivation was referred to as "desires" by Fishbein and Stasson included the item "I want to attend the telephone training session scheduled for my department". The authors reported that their measure of "desires" came close to capturing the meaning of intention. Behavioral expectation was referred to as "self-prediction" and was measured by the item "I will attend the telephone training session scheduled for my department".

Results from Fishbein and Stasson's (1990) study found that the addition of perceived behavioral control did not improve the amount of variance (58%) explained in employees' "desires" but did significantly improve the amount of variance explained in behavioral self-prediction (p < .01). In terms of predicting employees' attendance at the training session (B), the addition of PBC to the regression equation increased the explained variance from 9% to 11%, a nonsignificant change. Fishbein and Stasson's (1990) results, then, did not support either the PBC→BI or the PBC→B pathways.

The findings presented by Fishbein and Stasson (1990) are somewhat confusing. The authors report that more than half of the employees felt that their decision to attend or to not attend the training session was not under their control, thus suggesting that the behavior was involitional in nature. However, this perceived lack of control over the studied behavior did not influence employees' intentions or behaviors, but rather influenced behavioral self-predictions. One possible explanation for these results is an issue of construct specification and measurement. Specifically, the use of a "desire" rather than an "intention" measure may not have accurately reflected the BI construct. Another potential explanation is also a measurement issue. That is, the PBC measure may have been too weak or
unreliable to accurately contribute to the prediction of "desires" or behavior because: (1) it was a one-item scale, or (2) the scale was dichotomized at the midpoint rather than exhibiting the full range of behavioral control.

The other study not supporting the PBC—>BI pathway is one conducted by Hinsz and Nelson (1990) that examined faculty turnover intentions. This investigation tested four models, two of which were the TRA and the Theory of Planned Behavior, in predicting four intentions of university faculty members: (1) the intention to search for an alternative position during the current year, (2) the intention to search for an alternative position within the next two years, (3) the intention to resign from a current position during the current year, and (4) the intention to resign from a current position within the next two years. Hierarchical regression analyses indicated that adding perceived behavioral control as a determinant of behavioral intention did not significantly increase the amount of variance explained in any of the four intentions. Specifically, both the TRA and TPB explained 49% of the variance in intentions to search during the current year; the TRA and TPB explained 45% and 47%, respectively, of the variance in intentions to search within the next two years. In terms of intentions to resign during the current and within the next two years, the TRA explained 31% (current year) and 32% (next two years) of the variance and the TPB explained 37% (current year) and 38% (next two years) of the variance. Thus, this study fails to support the Theory of Planned Behavior. Furthermore, because the study did not attempt to predict behaviors, evidence either supporting or not supporting the PBC—>B pathway was not obtainable.

Hinsz and Nelson (1990) suggest that their study's lack of support for the Theory of Planned Behavior may be the result of faculty members' perception of substantial
control over this particular behavior. That is, the nature of academia (e.g. year long contracts) may influence how factors such as faculty members' perception of control over their behavior influence turnover intentions. Another factor possibly influencing this study's results, not mentioned by the authors, is the weakness of the PBC as well as all of the other models' measures. Specifically, for each behavioral intention, there were two direct ATT measures, one direct SN measure, and one direct PBC measure. Therefore, although the correlations between the two items measuring attitudes (i.e. search and resign) were high, the other measures may have been too unreliable to sufficiently contribute to the prediction of intentions.

Lastly, mixed support for the Theory of Planned Behavior has been found in studies examining modified models or models combined with other behavioral theories. For example, Ronis and Kaiser (1989) combined the TPB with the Health Belief Model to examine female college students' past and intended frequency of breast self-examination (BSE). The measure most related to perceived behavioral control (previously described in 'Determinants of PBC') measured "confidence in the ability to perform" BSE and was one (along with attitudes) of the strongest predictors of the behavior under study. However, a model combining the TPB with elements of the Protection Motivation Theory did not find an effect of the PBC measure on behavioral intention after attitudes were taken into account (Steffen, 1990). Finally, Brubaker and Fowler (1990) examined college males' performance of testicular self-examination (TSE) with a revised version of the TRA that included a measure of "self-efficacy". A path analysis provided support of the significant (p < .05) effect of "self-efficacy" on men's intention to perform TSE.

In summary, research by investigators other than Ajzen and his colleagues have provided mixed support for the Theory of Planned Behavior. In most of the
empirical studies discussed in this section that directly tested the TPB, the indirect effect of perceived behavioral control on behavior, i.e. PBC→BI, was documented. Evidence of the construct's direct impact on behavior, however, received much less support. Specifically, the PBC→B pathway was documented for only two behaviors: college students' weight loss (Netemeyer et. al., 1991, Study 2) and cancer screening participation by "high-risk" individuals (DeVellis et. al., 1990). Lastly, interaction effects were not found except in the study conducted by DeVellis et. al. (1990) in which a three-way interaction among knowledge, PBC, and BI in predicting cancer screening behavior for individuals at "high-risk" (p < .02). The major findings of these six empirical TPB studies are summarized in Table 4.

**Assessment of Mixed Empirical Support**

The empirical studies reviewed above have generated mixed support for the Theory of Planned Behavior. Several factors may contribute to this finding and merit discussion. These factors can be placed into three categories: (1) the theory's overall causal structure, (2) the conceptualization of the perceived behavioral control construct, and (3) the validity and reliability of the model as a whole as well as the measures developed for its constructs. Although all of these factors are very much interrelated, each is addressed separately because of its individual contribution to the Theory of Planned Behavior's empirical support. The first factor is discussed in detail; the others are addressed more briefly since they were extensively discussed in previous sections.
### Table 4

TPB: FINDINGS OF OTHER EMPIRICAL STUDIES

<table>
<thead>
<tr>
<th>INVESTIGATORS</th>
<th>BEHAVIOR</th>
<th>SUPPORT PBC--&gt;BI</th>
<th>BI:UNEXP&lt;sup&gt;a&lt;/sup&gt; VARIANCE</th>
<th>SUPPORT PBC--&gt;B</th>
<th>B:UNEXP VARIANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Netemeyer &amp; Burton (1990)</td>
<td>Voting</td>
<td>Yes</td>
<td>35%</td>
<td>No</td>
<td>65%</td>
</tr>
<tr>
<td>Netemeyer et. al. (1991) Study 1</td>
<td>Voting</td>
<td>Yes</td>
<td>57%</td>
<td>No</td>
<td>NR</td>
</tr>
<tr>
<td>Netemeyer et. al. (1991) Study 2</td>
<td>Weight loss</td>
<td>Yes</td>
<td>48%</td>
<td>Yes</td>
<td>92%</td>
</tr>
<tr>
<td>DeVellis et. al. (1990) &quot;High-risk&quot; cancer screening</td>
<td>Yes</td>
<td>79%</td>
<td>Yes&lt;sup&gt;b&lt;/sup&gt;</td>
<td>80%</td>
<td></td>
</tr>
<tr>
<td>DeVellis et. al. (1990) &quot;Ave-risk&quot; limit sugar</td>
<td>Yes</td>
<td>71%</td>
<td>No</td>
<td>73%</td>
<td></td>
</tr>
<tr>
<td>Beale &amp; Manstead (1990) Interview 1</td>
<td>Yes</td>
<td>84%</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Beale &amp; Manstead (1990) Interview 2</td>
<td>Yes</td>
<td>73%</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Fishbein &amp; Stasson (1990) Training attendance</td>
<td>No&lt;sup&gt;c&lt;/sup&gt;</td>
<td>42%</td>
<td>No</td>
<td>89%</td>
<td></td>
</tr>
<tr>
<td>Hinsz &amp; Nelson (1990) Search faculty turnover</td>
<td>No</td>
<td>53%</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Hinsz &amp; Nelson (1990) Resign faculty turnover</td>
<td>No</td>
<td>62%</td>
<td>NA</td>
<td>NA</td>
<td></td>
</tr>
</tbody>
</table>

NA = Not applicable because B not measured  
NR = Not reported  
a - Unexplained variance  
b - also found PBC x BI x knowledge interaction  
c - Used 'desire' measure
Reasons for mixed support: Overall causal structure. A discussion of possible reasons by which the overall causal structure of the Theory of Planned Behavior contributes to the mixed empirical evidence found in the reviewed investigations involves understanding the sufficiency of the model. To briefly summarize the process from which the Theory of Planned Behavior has evolved, the Theory of Reasoned Action is a model that has been extensively critiqued by those questioning its adequacy for predicting human behavior. Criticisms over the years have targeted: the causal relationships specified among the model's components; the variables that might improve the prediction of intentions or behaviors if they were incorporated in the model; and a major limitation of the model, namely its use for behaviors that are under complete volitional control. Undeniably, the parsimonious model proposed by Fishbein and Ajzen was rigorously challenged in terms of its sufficiency to predict human behavior.

The challenge of the TRA’s overall causal structure, or sufficiency, finally led to the incorporation of the perceived behavioral control construct, thus resulting in the Theory of Planned Behavior. As explained in the TRA's concluding remarks, the decision to expand or change the established model should have considered: (1) the theoretical justification of incorporating the perceived behavioral control construct and its pathways, and (2) the gain in the amended model's (i.e. TPB) predictive capability versus the loss in parsimony. The theoretical justification for incorporating perceived behavioral control in the TRA has been extensively addressed in an earlier section. The second consideration, i.e. the gain in predictive validity resulting from the incorporation of PBC versus the loss in parsimony, is discussed below.
The second consideration involves two components: (1) examining the gain in predictive capability by incorporating the perceived behavioral control concept and (2) evaluating the accompanying loss in parsimony by incorporating this additional construct. The first component is actually a question of the model's sufficiency as compared to the TRA. This issue can be addressed by comparing both models' ability to predict intentions and behavior.

The comparative ability of both the TRA and TPB to predict behavioral intentions and behavior in seven of the nine previously reviewed empirical studies is provided in Table 5. The other two studies (Fishbein and Stasson, 1990; Hinsz and Nelson, 1990) found no support for the Theory of Planned Behavior as specified by Ajzen and his colleagues. Potential errors in both selecting an involitional behavior to study and measuring PBC in these two studies were previously discussed and thus, they are not included in the table nor in further comparisons of the TRA and the TPB.

Table 5 shows that in terms of explaining more variance in behavioral intentions, the TPB outperformed the TRA. Specifically, the TPB explained an average of 18.4% (range 5 to 45%) more variance in behavioral intentions than TRA. In terms of increased ability to predict actual behavior, the TPB explained at least as much and in some cases significantly more variance than the TRA. The average increase of explained variance in behavior was 3.3 (range 0 to 13%). Those studies that did exhibit a significant PBC—>B effect tested the theory with behaviors that were relatively involitional in nature, such as weight loss (Schifter and Ajzen, 1985; Netemeyer et. al., 1991) and earning an 'A' in a specific course (Ajzen and Madden, 1986).
### Table 5

**TPB VERSUS TRA: PREDICTIVE ABILITY**

<table>
<thead>
<tr>
<th>INVESTIGATORS</th>
<th>BEHAVIOR</th>
<th>BI: EXP(^b) VARIANCE</th>
<th>B: EXP VARIANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schifter &amp; Ajzen</td>
<td>Weight loss</td>
<td>55 - 42 = 13(^c)</td>
<td>19 - 6 = 13(^c)</td>
</tr>
<tr>
<td>Ajzen &amp; Madden</td>
<td>Attending class</td>
<td>46 - 30 = 16(^f)</td>
<td>14 - 13 = 1(^d)</td>
</tr>
<tr>
<td>Study 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Getting 'A'</td>
<td>42 - 23 = 19(^f)</td>
<td>7 - 7 = 0(^d)</td>
</tr>
<tr>
<td></td>
<td>&quot;</td>
<td>41 - 24 = 17(^f)</td>
<td>20 - 15 = 5(^f)</td>
</tr>
<tr>
<td>Beck &amp; Ajzen</td>
<td>Cheating</td>
<td>67 - 45 = 22(^e)</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>Shoplifting</td>
<td>69 - 61 = 8(^e)</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>Lying</td>
<td>62 - 32 = 30(^e)</td>
<td>NR</td>
</tr>
<tr>
<td>Netemeyer &amp; Burton</td>
<td>Voting</td>
<td>65 - 20 = 45(^f)</td>
<td>35 - 35 = 0(^d)</td>
</tr>
<tr>
<td>Netemeyer et al.</td>
<td>Voting</td>
<td>44 - 18 = 26(^f)</td>
<td>7 - 7 = 0(^d)</td>
</tr>
<tr>
<td>Study 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study 2</td>
<td>Weight loss</td>
<td>52 - 16 = 36(^f)</td>
<td>8 - 4 = 4(^e)</td>
</tr>
<tr>
<td>DeVellis et al.</td>
<td>&quot;High-risk&quot; Cancer-screening</td>
<td>21 - 13 = 8(^f)</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td>&quot;Ave-risk&quot;</td>
<td>29 - 22 = 7(^e)</td>
<td>NR</td>
</tr>
<tr>
<td>Beale &amp; Manstead</td>
<td>Interview 1 Limit sugar</td>
<td>16 - 11 = 5(^f)</td>
<td>NA</td>
</tr>
<tr>
<td></td>
<td>Interview 2 &quot;</td>
<td>27 - 21 = 6(^f)</td>
<td>NA</td>
</tr>
</tbody>
</table>

NA = Not applicable b/c behavior not measured
NR = Not reported
d = Not significant
e = p < .05
a = Studies without PBC ---> BI are not included in table
b = Explained variance
c = Unreported significance
Evidence available to date, therefore, suggests that the Theory of Planned Behavior is a more adequate model than the Theory of Reasoned Action for explaining and predicting behaviors that are not fully under an individual's control. Because research is relatively limited, however, further empirical study is needed to validate these findings and to demonstrate similar effects under different conditions, populations, behaviors, etc. Determining whether or not the TPB's gain in predictability counterbalances its loss in parsimony appears somewhat more difficult to evaluate. The studies reviewed above indicate that the TPB's gain in predicting intentions was relatively substantial whereas its gain in predicting behavior was much less, perhaps due to the nature of the behaviors studied. These gains were achieved by incorporating one construct and adding two potential pathways (excluding correlations between PBC, SN, and ATT). While intuition might suggest that the TPB is still a more parsimonious model than other models proposed for predicting behavior (e.g. Liska, 1984; Triandis, 1977; Kuhl, 1984, 1985), the issue of gains versus losses pertain specifically to the TRA versus the TPB. Fortunately, methods exist that can objectively, rather than subjectively, address this issue.

One method for determining whether or not the predictability gained by the TPB is counterbalanced by the model's loss in parsimony is attainable by a structural equation analysis. This data analysis approach is discussed in much greater detail in Chapter III but suffice it to say at this time, indices can be attained for comparing differences between the TRA and the TPB that account for the model's ability to predict and its parsimony simultaneously.

The review of empirical literature that compared the TPB with the TRA included only one study using structural equation analysis that reported indices. Netemeyer et. al. (1991) used three such indices for comparisons between the TRA, the TPB-1
(with PBC→BI pathway only) and the TPB-2 (with PBC→BI and PBC→B pathways). The authors found that the TPB-1 was a significantly better model, in terms of parsimony and sufficiency, i.e. its ability to predict, than the TRA for predicting student voting behavior. For predicting students' weight loss, the indices showed that the TPB-1 was significantly better than the TRA and the TPB-2 was significantly better than TPB-1.

Research conducted to date, therefore, suggests that the gain in sufficiency by extending the TRA to the Theory of Planned Behavior balances the loss in parsimony. However, subjective evidence is relatively limited at this time and objective documentation is even more limited. Support for the overall causal structure of the Theory of Planned Behavior is also gained by the theoretical justification for including PBC in the TRA, as was discussed in a previous section. Further support can be gained from future studies that examine the predictive differences between the two models, preferably with structural equation analysis.

A final factor with respect to the model's overall causal structure that potentially contributes to the mixed empirical support of the Theory of Planned Behavior also pertains to the model's sufficiency. As previously defined, a sufficient model is one that contains all the factors in the set of determinants and thus, accounts for all nonerror variance in the behavior, i.e. accounts for all variance not due to systematic or random error. Although the TPB is apparently more sufficient than the TRA, substantial variance in both intentions and behavior is yet unexplained by the Theory of Planned Behavior. According to Tables 3 and 4 (see pp. 102, 113), the amount of unexplained variance has ranged from 31% to 84% and 45% to 93% in behavioral intentions and behavior, respectively. Although much of this may be error variance, two other sources are offered as reasons for unexplained variance.
First, one obvious reason for the substantial amount of unexplained variance is that the set of factors determining all of the nonerror variance in intentions and behavior is incomplete. Similar to the research conducted with the TRA, investigators have tested whether including other variables in the TPB would increase the predictive ability of the model. Again, one of the more popularly suggested variables has been past behavior because of its link to perceived behavioral control. Since this variable has been thoroughly addressed in the previous section pertaining to the conceptualization of perceived behavioral control, it is not further discussed here. Other variables that have been included in the TPB's regression model or assessed for their moderating effects on the model are: moral obligations (Beck and Ajzen, 1991); development of a detailed plan of action (Schifter and Ajzen, 1985); ego strength (Schifter and Ajzen, 1985); attitude toward the object, i.e. training (Fishbein and Stasson, 1990); direct experience with the behavior (Beale and Manstead, 1991); and knowledge (DeVellis et. al., 1990).

A second possible reason for the amount of unexplained variance is a methodological issue of scaling. Bagozzi (1984) and Ajzen (1991) have addressed this issue in critically assessing expectancy-value and other multiplicative models such as the Theory of Reasoned Action or the Theory of Planned Behavior.

In most applications of the TRA and the TPB, beliefs, evaluations, etc., have been measured on 7-point scales scored in either a bipolar (-3 to +3) or a unipolar (1 to 7) fashion. There is nothing in the theory of either the TRA or the TPB to suggest that the scales should be scored one way or the other; both methods can be reasonably supported. Rating scales such as those used in the TRA and TPB are at best equal-interval measures. As such, going from a bipolar to a unipolar scale (or vice versa) is simply a matter of adding or subtracting a constant, i.e. linear
tranformation. If the scales were used as independent measures, transforming one type of scale (e.g. bipolar) to the other type (e.g. unipolar) would present no problem. Problems may arise, however, in models that multiply two measures.

In models that include at best equal-interval measures, the linear transformation of one or both of the measures that are multiplied does not result in a linear transformation of the product. Therefore, widely different results can be generated for different types of scaling and the results obtained in one situation are not invariable to another situation. This is not a problem if the measures to be multiplied are ratio-scaled. However, according to Bagozzi (1984), researchers using multiplicative models have assumed that the measures being multiplied, such as beliefs and evaluations, are ratio-scaled. In making this assumption, researchers may provide misleading results about the amount of variance explained in a criterion from a predictor.

Recent empirical work conducted by Ajzen (1991) demonstrates how the prediction of intentions and attitudes can vary depending on how multiplied measures are scored. This work supports the contention that a substantial amount of unexplained variance found in current empirical studies of both the TRA and the TPB may be influenced by this fundamental scaling problem. Since neither theory suggests how the scales should be score, researchers can manipulate the scoring of scales in an effort to increase the model’s predictive capability and thus, decrease the amount of unexplained variance in behavioral intentions and behavior. Bagozzi (1984) cautions, however, that schemes to satisfy predictive validity may fail to lead to convergent and discriminant validity and thus, generate invalid results.

In summary, the Theory of Planned Behavior has been critically evaluated in terms of its relative and absolute sufficiency in predicting behavioral intentions and
behavior. This section has offered several reasons by which the overall causal structure of the Theory of Planned Behavior may have contributed to the mixed support of the empirical studies reviewed in this section. For example, the sufficiency of the Theory of Planned Behavior has been questioned, in terms of variables other than those included in the model (e.g. moral obligations, ego strength, knowledge, past behavior, etc.) that might impact or moderate the formation of intentions or the performance of behavior. In addition, the fundamental problem with scaling associated with multiplicative models such as the Theory of Planned Behavior has been discussed as a potential contributor to distortions in the empirical results.

**Reasons for mixed support: Conceptualization.** The conceptualization of perceived behavioral control and researchers' operationalization of the construct in empirical investigations have been thoroughly discussed in a previous section. However, these issues have not been addressed in the context of the studies' results. This section briefly compares results from empirical studies with characteristics of the conceptualization and operationalization of perceived behavioral control in an effort to identify any patterns of relationships between the two. More specifically, the level of conceptualization of the PBC construct is compared to the outcomes of the conceptual process, i.e. the empirical results. This comparison may be helpful for determining whether the currently accepted conceptualization of perceived behavioral control is adequate or if it contributes to the theory's mixed empirical support.

The majority of work in conceptualizing perceived behavioral control has been provided by Ajzen and his colleagues. As discussed in the section addressing the
determinants of PBC, Ajzen and Madden's (1986) conceptualization of the construct led them to identify salient factors (i.e. control beliefs), underlying an individual's perception of behavioral control, that could facilitate or inhibit the behavior under study. These control beliefs were used to develop the belief-based PBC measures for their two studies. The direct measures of perceived behavioral control developed by Ajzen and Madden were similar in design to the direct measures of attitude, subjective norm, and behavioral intention. Other researchers have followed the direction taken by Ajzen and his colleagues in developing their direct PBC measures. These measures have included one to four items, similar or identical to the ones developed by Ajzen and his associates (Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Beck and Ajzen, 1991). The empirical studies conducted by other investigators, then, have not furthered the conceptualization of the perceived behavioral control construct or its operationalization. Thus, the currently accepted level of the construct's conceptualization remains as theorized by Ajzen and his colleagues.

The level of any construct's conceptualization is an abstract and indeterminate concept. However, an indicator may be helpful in reflecting the conceptual level of the construct. One indicator that potentially fits this description is the manner in which the construct has been operationalized, i.e. the construct's measures. The measures developed for estimating the perceived behavioral control concept include the direct and belief-based scales that are summarized in Tables 1 and 2 (see pp. 77-78). In comparing the measures used to estimate perceived behavioral control with the results of the reviewed empirical investigations, one can specify characteristics that may be helpful in this process. In terms of measures of perceived behavioral control, three characteristics can be identified: (1) the type of scale, i.e. direct or
belief-based, (2) the number of items included in the measure, and related to the second characteristic, (3) the measures' reliability. Results that seem most useful for a comparison process include support for both the PBC—>BI and PBC—>B pathways and the amount of unexplained variance in behavioral intentions and behavior. These specific results are included in Tables 3 and 4 (See pp. 102, 113).

The type of scales used in the investigations are first compared to the results followed by a discussion of the number of items in the measures and the measures' reliability.

To identify any patterns of relationships between the type of scale used to measure perceived behavioral control and specific study results, the results from belief-based measures can be compared to the results from the direct PBC measures. Belief-based PBC measures were only used by Ajzen and Madden (1986) in their study of two college students' behaviors: attending class and getting an 'A' in a specific course. The correlations between these measures and their corresponding direct PBC measures were relatively adequate (range of .54 to .63), suggesting that the one type of measure corresponded with the other. The results reported from both studies were generated by hierarchical regression analyses that used direct measures for all the determinants of intentions. The authors note, but do not report, that similar results were found when the belief-based PBC measures were used in the regression equations. Since specific results were not available from belief-based measures, using the type of scale to seek patterns in the empirical results that might contribute to the theory's mixed support is not attainable at this time.

In terms of identifying a relationship between the number of items in the direct PBC measures and the mixed empirical results, the measures consisting of fewer items can be compared to those with more items. This characteristic, i.e. number of
items in a scale, is an issue of the measures' reliability. The reliability of the measures used in the empirical investigations reviewed in this chapter is important in assessing the construct validity of perceived behavioral control concept. This topic is discussed in greater detail in Chapter III but suffice it say at this point, construct validity refers to the ability of the items selected for inclusion in the direct PBC scales to validly measure the construct of perceived behavioral control. Standards of reliability have been provided by Nunnally (1978, p. 245) and depend on how a measure is being used. For measures used in early stages of research, reliabilities of .70 or higher are sufficient; for basic research, striving for reliabilities greater than .80 may be wasteful in time and funds.

The reliability of the direct PBC measures developed by Ajzen and his colleagues varied widely (see Table 1, p. 77). In using the standard of reliability for early stages of research (.70), nearly four of the ten measures with reported coefficient alphas met the criterion: the global and belief-based measures in Study 1; and the global measures used in both waves of Study 2 conducted by Ajzen and Madden (1986). In the studies reporting interitem correlations (Schifter and Ajzen, 1985; Beck and Ajzen, 1991), only one of the measures used in predicting four behaviors was acceptable (r = .63).

No pattern of relationships is apparent between the reliability of the PBC measures and the number of items included in the scales. In addition, a relationship between the measures' reliability and the PBC---BI pathway provides no obvious pattern (see Table 3, p. 102). Interestingly, however, the direct PBC measures with the lowest interitem correlation, i.e. Beck and Ajzen (1991), were in the studies that predicted the most variance in both intentions and behavior. Furthermore, these measures were associated with some of the highest increases in the amount of
variance explained in behavioral intentions when the PBC--->BI pathway (see Table 5, p. 116).

Turning attention to the direct PBC measures developed by other investigators, the measures meeting the standard reliability criterion are ones consisting of four items (see Table 2, p. 78). For the measures consisting of only one item, reliability, or internal consistency, is not an issue. Although studies that include more than one-item PBC measure are limited, it appears that the measures with more items have higher reliability coefficients. In addition, of the studies that did support the PBC--->BI pathway, the ones that had the higher reliability coefficients explained more variance in behavioral intentions than those with lower coefficients (see Table 4, p. 113). Contrary to the research of Ajzen and his associates, the studies with the higher reliability coefficients (Netemeyer and Burton, 1990; Netemeyer et. al., 1991) were associated with the higher increases in explained variance when the PBC--->BI pathway was added (see Table 5, p. 116).

To summarize the results at this point, it seems reasonable to suggest that characteristics of the measures developed and used for estimating perceived behavioral control may be associated with specific results of the reviewed studies. However, consistent patterns of relationships between the measures' characteristics, in terms of quality (reliability) and quantity (number of items) and specific results are not obvious. If the set of PBC measures developed to date are acceptable as an indicator of the level of the construct's conceptualization, some empirical investigations reviewed in this chapter lend support to the current approach toward conceptualizing perceived behavioral control. Data, however, is very limited and other factors temper this support.
As previously reported, the amount of unexplained variance in the Theory of Planned Behavior is relatively high, ranging from 31% to 84% and 45% to 93% in behavioral intentions and behavior, respectively. Accordingly, reasons must exist for this finding. Several factors have been suggested in this section as contributors to the substantial amount of the unexplained variance. However, in spite of its demonstrated role in the model, it seems particularly reasonable to question the conceptualization and subsequent operationalization of the perceived behavioral control concept for several reasons.

First, the tables discussed in this section demonstrate that while the addition of a PBC measure usually increased the amount of variance explained in behavioral intentions, a substantial amount of variance can not be explained. Furthermore, reasons for this amount of unexplained variance do not follow an obvious pattern. The tables also indicate that the measures based on the current level of PBC's conceptualization have been oftentimes insufficient or so simplistic that their reliability can not be assessed.

Second, the Theory of Planned Behavior is yet in its infancy state and limited research has been generated to allow an adequate evaluation of the role of perceived behavioral control and the theory. Further investigation of this construct in different populations, studied behaviors, etc. could help clarify whether its conceptualization is contributing to the mixed empirical support.

Finally and perhaps most importantly, the current level of conceptualization of perceived behavioral control lags substantially behind the level at which attitude and subjective norm are conceptualized. Ajzen and Madden (1986) have developed the most rigorous measures published to date. Although their attempt to measure the construct's "control beliefs" is theoretically based, the logic behind determining the
frequency or likelihood that inhibiting and facilitating factors occur seems to not encompass the entire PBC concept. In addition, it appears that since belief-based measures have included both frequency and likelihood scales, the conceptual basis underlying perceived behavioral control is ambiguous. Other researchers have ignored the belief-based measure in developing their measures and thus, further information regarding this possible route for estimating perceived behavioral control has not been provided. The conceptual processes and subsequent operationalizations of both attitudes and subjective norms were progressive in nature. It is reasonable to suggest that the conceptualization of perceived behavioral control will mature as it is studied and perhaps increase its contribution to the amount of explained variance in behavioral intentions and behavior.

Reasons for mixed support: Validity and reliability. The validity and reliability of the Theory of Planned Behavior and its measures have been thoroughly addressed in previous sections. Since this topic overlaps considerably with the discussions regarding how and why other factors may contribute to the mixed empirical support, it is only briefly considered here.

Two issues of validity and reliability that may have played a role in contributing to the mixed support should be discussed: (1) the dimensionality of constructs in the models, and (2) measurement error. In terms of the dimensionality issue, previous research findings suggest that the antecedents of both attitudes and subjective norms are better represented by a multidimensional rather than a unidimensional structure. However, the Theory of Planned Behavior maintains the stance taken in the Theory of Reasoned Action, namely multidimensional representations of expectancy-value attitude, the normative belief-motivation to comply composite, or the antecedent of
perceived behavioral control are not supported. As previously discussed, however, erroneous assumptions about constructs' dimensionality and their subsequent measurement can result in invalid predictions of intentions and behavior. Since the empirical studies of the Theory of Planned Behavior reviewed in this chapter did not consider the dimensional nature of any of the model's constructs, it is reasonable to suggest that the regression coefficients and correlations may not validly represent the true amount of variance explained in behavioral intentions and behavior.

Finally, measurement error is guaranteed in virtually any data collection instrument and study methodology, leading to substantially distorted results. The issue can be confronted, however, and mechanisms are available for assessing and eliminating its effects. In the analyses of all but one of the empirical studies, the Theory of Planned Behavior was tested with multiple or hierarchical regression analyses. The correlations and regression coefficients attained from these types of analyses can be attenuated due to error in the measured variables. In using structural equation analysis, measurement error is simultaneously assessed with the model's theoretical structure, thus providing truer pathway coefficients. Although further explanation is provided in the next chapter, coefficients of the model's structure independent of any measurement error is also attainable with this type of multivariate data analysis. The lack of support for PBC's direct and/or indirect effect on behavior may reflect the attenuation associated with unreliable measurement of the latent variables included in the Theory of Planned Behavior.

TPB: Concluding Remarks

The Theory of Planned Behavior is an extension of the Theory of Reasoned Action. Its emergence in the literature during the mid 1980s was accompanied by
Ajzen's acknowledgement that involitional behavior was more the norm than the exception and thus, the TRA was limited in its uses to predict human behavior. With this admission and the model's introduction, Ajzen addressed many of the criticisms targeted at the Theory of Reasoned Action. Specifically, by proposing that "perceived behavioral control" be included in the model, Ajzen not only recognizes the frequency in which involitional behavior occurs but also that: (1) different behavioral processes underlie volitional and involitional behaviors, (2) behaviors vary in the extent to which they are under an individual's control, and (3) accounting for factors that influence the "move" from intentions to behavior improves the model's predictive utility, i.e. sufficiency. In short, the Theory of Planned Behavior has provided a theoretical basis for predicting behavior, regardless of its position on the continuum of behavioral control. The flexibility added to the model by incorporating the concept of perceived behavioral control is congruent with recommendations of other researchers, such as Triandis (1977), Kuhl (1984; 1985), Liska (1984), and Bandura (1977; 1982).

The current level at which perceived behavioral control is conceptualized leads to a major research concern: the antecedent of the construct. Unlike attitude and subjective norm, the task of identifying the antecedent of perceived behavioral control remains relatively untouched. Ajzen and his colleagues have proposed that a set of "control beliefs" underlie the concept but have yet to expound on this issue. The conceptual development of perceived behavioral control can be furthered by study of the construct's antecedent.

Empirical support for the Theory of Planned Behavior and the role of perceived behavioral control in determining intentions and behavior is limited compared to the Theory of Reasoned Action. In addition, the empirical research published to date
has been conducted with student populations. These findings are not unexpected since the model is relatively new to the literature and student populations are easily accessible to researchers. Few studies have included belief-based measures of attitudes and subjective norms and only one investigation has used a belief-based PBC measure. Therefore, the theory in its entirety has not been tested.

The investigations that have tested the theory have provided mixed support. For the most part, studies have supported the motivational or indirect effect of perceived behavioral control on the prediction of behavior. On the other hand, less support has been generated for the nonmotivational or direct effect of the construct on behavior.

Several factors that could contribute to the theory's mixed support have been offered in this discussion, including: (1) misspecification of the model's overall causal structure, i.e. absence of other variables that might improve the model's predictive utility, (2) scaling problems associated with multiplicative models, (3) the level of conceptualization of the perceived behavioral control construct, (4) the extent to which the construct has been adequately operationalized, (5) the misspecification of the constructs' dimensionality, and (6) the extent of measurement error in the data collection instrument and the study methodology.

In summary, the Theory of Planned Behavior has shown some value in predicting behaviors that are not completely volitional in nature. However, further study is needed to evaluate the model's sufficiency in predicting human behaviors differing in nature, in different populations, and for different situations. In addition, further study is necessary to address issues relating to the conceptualization and measurement of the perceived behavioral control construct. Lastly, additional research is required to further validate the model's overall causal structure.
Study Rationale

The previous two sections in this chapter have thoroughly discussed two behavioral intention models, the Theory of Reasoned Action and the Theory of Planned Behavior. This in-depth review was necessary to provide the basis for the rationale of the current investigation. The present section addresses the reasons that the Theory of Planned Behavior was selected as the framework for studying the spontaneous reporting of serious adverse drug events to the FDA by physicians. Second, this section develops the model that is used for such a study and discusses the rationale for its development. In addition, the specific research questions and the hypotheses developed for testing them are presented.

Rationale for Using the Theory of Planned Behavior

Understanding the spontaneous reporting behavior of physicians can be assisted by selecting an appropriate theoretical framework, or model, for examining the determinants of the behavior. Although numerous models have been developed, the multi-attribute or expectancy-value models has been one of the most dominant group of models, particularly within the psychology literature (Lutz, 1981; Engel et. al., 1986). Multi-attribute models have been particularly important because the theory underlying them specifies a causal relationship flowing from cognitive structure to attitude, thus providing diagnostic utility.

Several multi-attribute models exist in the literature but the group of models most widely recognized and frequently used, however, are the behavioral intention models proposed and developed by Fishbein, Ajzen, and colleagues. Two behavioral intention models have been thoroughly discussed in this review of
literature: (1) the Theory of Reasoned Action, also known as the Fishbein Behavioral Intention Model, (2) and the Theory of Planned Behavior.

To briefly summarize, the Theory of Reasoned Action has been widely applied over the past two decades in a variety of behavioral settings to explain and predict human behavior. Although the theory has been largely successful, it has been repeatedly criticized for a major shortcoming, its insufficiency in predicting behaviors that are not completely volitional in nature. The introduction of 'perceived behavioral control' as a third determinant of behavioral intentions resulted in the birth of the Theory of Planned Behavior in the mid 1980's.

Since the Theory of Planned Behavior is an extension of the Theory of Reasoned Action, the new model has gained support from researchers' experience with its predecessor. Investigations with the new model are relatively limited but studies comparing it with the TRA have found that, in most cases, the addition of perceived behavioral control significantly increased the amount of variance explained in behavioral intentions. A few studies have also demonstrated an increase in the amount of variance explained in behavior. This latter finding has been found with behaviors that are considered to be relatively involitional in nature.

The Theory of Planned Behavior, then, is designed to explain and predict behaviors of any involitional nature. Accordingly, three scenarios can be proposed: (1) If the behavior under study is involitional to any degree, the theory predicts that perceived behavioral control has a motivational, or indirect, effect on behavior that is mediated by intention, (2) If the behavior under study is relatively involitional in nature, perceived behavioral control has the indirect effect on behavior as well as a direct effect, as long as the individual's perception of control reflects his actual control with a reasonable degree of accuracy, (3) If the behavior under study is
completely volitional, the perceived behavioral control concept is irrelevant to explaining or predicting the behavior, the construct drops out of the model, and the resultant model is the more parsimonious Theory of Reasoned Action.

The selection of a model for this investigation considered the advantages of the multi-attribute models, the behavioral intention models as a category of the multi-attribute models, and the Theory of Planned Behavior as a member of the behavioral intention models. First, a multi-attribute model was preferred because its theoretical structure could provide reasons for the behavior of physicians with respect to spontaneously reporting adverse drug events.

Second, a behavioral intention model was favored because a substantial number of studies had successfully applied this type of model. In addition, reporting behaviors of physicians could not be practically measured by either direct observations or self-report methods in this investigation because: (1) reports of adverse drug events submitted to the FDA by physicians are kept confidential and cannot be released for research outside the FDA, and (2) serious adverse drug events occur infrequently in some physicians' practices and thus, obtaining a self-report measure at any specified time may either not allow enough time for one to occur or allow too much time for a successful follow-up. Since obtaining a measure of behavior was not feasible, a measure of behavioral intention seemed the next most desirable measure.

Finally, the Theory of Planned Behavior was preferred because it was applicable to behaviors of any nature. Based on the research of Rogers et. al. (1988) that was discussed in the first chapter, it seemed reasonable to expect that a physician would perceive some lack of control over reporting to the FDA since factors, such as time or professional obligation, might influence whether or not he was able to act on his
intention. Therefore, the Theory of Planned Behavior was selected as the framework for developing a model to predict spontaneous reporting by physicians. If physicians' reporting behavior was, in fact, completely volitional in nature, the concept of perceived behavioral control would be irrelevant to the behavioral model and the Theory of Planned Behavior would be reduced to its more parsimonious model, the Theory of Reasoned Action.

Development of the Model and Research Hypothesis

The Theory of Planned Behavior, as prescribed by Ajzen and his colleagues, is the foundation of the model used in this investigation for predicting physicians' intentions to spontaneously report serious adverse drug events to the FDA. This model has been previously defined and illustrated in Figure 3 (See p. 65). This investigation has several research objectives that are addressed in the following discussions of: (1) the structure of the expectancy-value attitude construct, (2) the structure of the normative belief-motivation to comply construct, (3) the determinant or antecedent of perceived behavioral control, (4) the structure of the antecedent of the perceived behavioral control construct, (5) the role of perceived behavioral control in the Theory of Planned Behavior, (6) the role of past behavior in the Theory of Planned Behavior, and (7) other issues related specifically to this investigation's model. Finally, the model developed in this investigation to explain physicians' intentions to spontaneous report a serious adverse drug event to the FDA and some additional hypotheses pertaining to this overall model are presented.
Structure of Expectancy-Value Attitude Construct

One objective of this research is to examine the structure of the expectancy-value attitude construct in the context of the Theory of Planned Behavior. This objective is addressed in Research Question 1 and the development of Hypothesis 1.1.

Research question 1. What is the structure, or underlying dimensional nature, of expectancy-value attitude within the Theory of Planned Behavior? Does this study's results support previous research with the Theory of Reasoned Action finding that the antecedent of attitude toward the behavior is better represented with a two-dimensional rather than a unidimensional structure?

Development of research hypothesis. According to the Theory of Planned Behavior and the Theory of Reasoned Action, the belief-based attitude measure, derived from expectancy value theory, assumes that attitude is a function of all salient beliefs. Therefore, the dimensionality of expectancy-value attitude is not an issue with the present depiction of the Theory of Planned Behavior. That is, the structure of expectancy-value attitude is defined as unidimensional in nature.

All investigations of the Theory of Planned Behavior have, for the most part, accepted expectancy-value attitude as a unidimensional construct. This finding is most likely based on the definitions of the model's components provided by Ajzen and his colleagues (Ajzen, 1985; Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Beck and Ajzen, 1991). However, most of the studies conducted to date would not have been able to test the dimensionality of the belief-based measures because the studies only included direct measures of attitude, subjective norm, and perceived behavioral control. One investigation did develop belief-based measures
for attitude and subjective norm but summed the scales as if they represented a unidimensional construct (Fishbein and Stasson, 1990). Another study, conducted by DeVellis et al. (1990), however, supported a two-factor model for expectancy-value attitude in which one factor represented "efficacy" and the other represented "barriers" to participating in cancer screening.

In the literature reviewing the Theory of Reasoned Action, a multidimensional structure of the expectancy-value attitude construct has been supported over the unidimensional representation (Bagozzi, 1981a; Bagozzi, 1981b; Burnkrant and Page, 1988). This investigation uses the Theory of Planned Behavior to test this hypothesis in examining physicians' attitudes with respect to their spontaneously reporting serious adverse drug events to the FDA. This study proposes the number and nature of the dimensions representing expectancy-value attitude based on two sources: (1) the research of Rogers et al., and (2) the research of Burnkrant and Page.

The research of Rogers et al. (1988, p. 1597) measured "attitudes" toward the FDA's spontaneous reporting system and ADE reporting in general. The measurement of "attitudes" consisted of two belief statements with respect to the FDA and seven belief statements pertaining to ADE reporting in general. These statements have been previously discussed in Chapter I and thus, are not presented in full here. In general, each belief statement can be interpreted as an advantage or disadvantage of the FDA's SRS or the reporting process. For example, beliefs interpretable as a disadvantage include: (1) "It takes too much time to report adverse drug events" and (2) "If I report an adverse drug event, I increase my own liability". Beliefs interpretable as an advantage, however, are fewer and much less obvious. The process by which the belief statements were obtained by Rogers et al.
was not described and thus, the saliency of the beliefs is unknown. However, their content or nature, i.e. advantages and disadvantages, can serve as a guide for proposing the number and the nature of dimensions in this investigation.

The second source used in this study for proposing the dimensions of expectancy-value attitude is the research conducted by Burnkrant and Page (1988). This study supported a two-dimensional structure for expectancy-value attitude in which one dimension represented positive consequences and the other represented negative consequences of donating blood. The authors theoretically supported the two dimensions with research conducted in the information processing literature pertaining to memory. This research suggests that memory is a network of associations in which objects, ideas, individuals, etc. are linked together based on learning experiences. Therefore, they proposed that the act of donating blood was a node in memory in which linkages among the positive and among the negative consequences were stronger than the linkages between positive and negative consequences of giving blood.

In terms of this investigation, two dimensions underlying expectancy-value attitude are proposed: one dimension representing the positive consequences of reporting a serious adverse drug event to the FDA and the other dimension representing the negative consequences of reporting (See Figure 4). The number and nature of these two dimensions seems reasonable based on the positive- and negative-type belief statements selected for study by Rogers et. al. (1988) and the evidence provided by Burnkrant and Page (1988). Although the behavior under study in this investigation is different than that studied by Burnkrant and Page, the nature of their dimensions, i.e. positive and negative consequences, is relatively generic in applicability and can be theoretically supported in this study.
Panel A: Unidimensional EV

Helps ADE Data Base
Discourages High-risk Drugs
Prevents Damaging ADE
Fulfills Obligation
FDA Scrutinizes Drug
Takes Time
Paperwork
Legal Threat

Panel B: Multidimensional EV

Helps ADE Data Base
Discourages High-risk Drugs
Prevents Damaging ADE
Fulfills Obligation
FDA Scrutinizes Drug
Takes Time
Paperwork
Legal Threat

Figure 4: Dimensionality of EV Composite
Following the theoretical approach suggested by Burnkrant and Page (1988), this investigation proposes that the act of reporting an adverse drug event can be represented as a node in memory. Since associations within the memory network may be linked together based on learning experiences, it is reasonable to hypothesize that the linkages among the positive consequences and among the negative consequences are stronger than the linkages between positive and negative consequences of reporting a serious adverse event. For example, it is reasonable to expect that "reporting takes too much time" and "reporting increases my own liability" are more strongly linked in memory than "reporting takes too much time" and "reporting fulfills my professional obligation". The actual consequences are based on the results of exploratory research.

In summary, based on the review of literature and the theoretical support provided above, this investigation proposes that expectancy-value attitude is better represented by a two-dimensional rather than a uni-dimensional structure. This two-dimensional structure is proposed to include one dimension representing positive consequences and a second dimension representing negative consequences of reporting a serious adverse drug event to the FDA. These propositions are tested in Hypothesis 1.1.

**Hypothesis 1.1:**

H1.1: A two-dimensional model of expectancy-value attitude in which one dimension represents the positive and the other represents the negative consequences of reporting a serious ADE to the FDA will provide a significant improvement in fit to the data over a unidimensional representation of expectancy-value attitude.
Structure of Normative Belief-Motivation to Comply Construct

A second objective of this research is to examine the structure of the normative belief-motivation to comply composite underlying subjective norm in the Theory of Planned Behavior. This objective is addressed in Research Question 2 and the development of Hypothesis 2.1.

Research question 2. What is the structure, or underlying dimensional nature, of the normative belief-motivation to comply construct within the Theory of Planned Behavior? Does this study's results support previous research with the Theory of Reasoned Action finding that the antecedent of subjective norm is better represented as a two-dimensional rather than a unidimensional structure?

Development of research hypothesis. According to the Theory of Planned Behavior and the Theory of Reasoned Action, the normative belief-motivation to comply composite underlying subjective norm is also a function of all salient beliefs. Therefore, similar to expectancy-value attitude, this composite's dimensionality is not an issue because its structure is defined as unidimensional in nature.

Similar to the finding with expectancy-value attitude, all investigations of the Theory of Planned Behavior published to date have accepted a unidimensional representation of the normative belief-motivation to comply composite. Again, this finding is most likely due to the definition and the measurement approach provided by Ajzen and his colleagues (Ajzen, 1985; Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1987; Ajzen, 1988; Beck and Ajzen, 1991). However, only two studies, excluding Ajzen and Madden (1986), included belief-based measures of subjective norm and thus, could have tested the assumption of a unidimensionality.
The studies conducted by Fishbein and Stasson (1990) and DeVellis et. al. (1990) included four and three normative referents in their belief-based measure, respectively. Although DeVellis et. al. do not report specific results pertaining to the strength or impact of normative beliefs on intentions, the results of Fishbein and Stasson's study demonstrated that for most participants, beliefs about their supervisor/boss and coworkers differed from beliefs about friends and spouse/roommate. Therefore, although these studies did not specifically examine the dimensionality of the normative belief-motivation to comply composite, the study conducted by Fishbein and Stasson suggests that this construct may consist of more than one dimension.

The literature reviewing the Theory of Reasoned Action also provides support for a multidimensional representation of the normative belief-motivation to comply construct. The research conducted by Grube et. al. (1986), previously discussed in this chapter, suggests that this construct may be multidimensional in nature. Bumkrant and Page (1988) specifically tested the dimensionality of the NBMC composite and found that the construct exists as a two-dimensional structure for the act of donating blood. In this study, the authors proposed one dimension representing friends and spouse and the other dimension representing parents and employer with the same theoretical approach used to support the two-dimensional representation of expectancy-value attitude, i.e. the network representation of memory.

This investigation also follows the approach undertaken by Bumkrant and Page (1988) in proposing a two-dimensional structure representing the normative belief-motivation to comply composite that underlies subjective norm. Specifically, it is reasonable to hypothesize that the node of memory representing the act of reporting
a serious adverse drug event to the FDA contains linkages between salient referents. The referents found to be salient in this investigation included: (1) the FDA, (2) hospital licensing committees, (3) hospital committees, (4) national and state medical organizations, (5) specialty practice organizations, (6) colleagues, and (7) pharmaceutical manufacturers including their sale representatives.

Prior research with physicians' reporting intentions or behavior has neither identified salient referents nor provided a reason for their classification into groups. However, it seems reasonable to propose that the referents identified in this investigation belong to one of two groups: (1) a group that has regulatory or authoritative power over a physician, his practice, or the hospital in which the physician has staffing privileges, and (2) a group that has no authoritative power but instead, operate at a peer, professional, or associate level with the physician. The 'authoritative' (A) group includes the FDA, hospital licensing committees, and hospital committees whereas the nonauthoritative (NA) group includes the other four salient referents: national and state medical organizations, specialty practice organizations, colleagues, and pharmaceutical manufacturers and their sale representatives. Similar to expectancy-value attitude, salient referents were identified in exploratory research.

This investigation proposes, then, that the linkages among the 'authoritative' referents and the among the 'nonauthoritative' referents are stronger than the linkages between the 'authoritative' and 'nonauthoritative' referents with respect to spontaneously reporting a serious ADE to the FDA. For example, it is reasonable to expect that the FDA and hospital licensing committees are more strongly linked in memory because they may represent a threat to the physician, i.e. outsiders who dictate the physician's practice style, require the physician to complete paperwork or
comply with rules, etc. On the hand, 'nonauthoritative' referents have little if any official regulatory power over the physician or his practice and thus, may be perceived as nonthreatening.

In summary, this investigation proposes that the normative belief-motivation to comply composite that underlies subjective norm (hereafter labeled GSN to distinguish it from the measured SN variable) is better represented by a two-dimensional rather than a unidimensional structure (See Figure 5). One of the dimensions represents 'authoritative' (A) referents and the second dimension represents 'nonauthoritative' (NA) referents with respect to physicians' reporting of a serious adverse drug event to the FDA. These propositions are tested in Hypothesis 2.1.

**Hypothesis 2.1:**

H2.1: A two-dimensional model of the normative belief-motivation to comply (NBMC) composite in which one dimension represents 'authoritative' and the other represents 'nonauthoritative' referents will provide a significant improvement in fit to the data over a unidimensional representation of the NBMC composite.

**Antecedent of Perceived Behavioral Control**

The focus of this investigation and hence, one of the most important objectives, is to examine the antecedent of the perceived behavioral control construct in the Theory of Planned Behavior. This objective is addressed in Research Question 3 and the development of Hypothesis 3.1.
Panel A: Unidimensional NBMC

Panel B: Multidimensional NBMC: 'Authoritative' and 'Nonauthoritative'

Figure 5: Dimensionality of NBMC Composite
Research question 3. What is the antecedent of perceived behavioral control? Does an antecedent consisting of a composite of control beliefs and the strength of their influence over an individual's performance of the behavior provide a better representation of the perceived behavioral control construct than the set of 'control beliefs' as proposed by Ajzen and his colleagues?

Development of research hypothesis. The current approach for conceptualizing the perceived behavioral control construct has been thoroughly addressed in previous sections. This section briefly summarizes the primary issues pertaining to this approach and then presents the conceptual approach proposed by this investigation.

Ajzen's approach for conceptualizing perceived behavioral control has been primarily discussed in terms of the construct's conceptual definition and operationalization. As previously explained, this approach is similar, in part, to the approach for conceptualizing attitude and subjective norm. Specifically, similar to the set of salient behavioral and normative beliefs presumably underlying attitude and subjective norm, respectively, a set of "control beliefs" presumably underlies perceived behavioral control. Beyond this point, however, the conceptualization of perceived behavioral control differs from the approach taken by attitude and subjective norm with respect to two issues: (1) the conceptual definitions of the sets of beliefs and (2) the conceptual definitions of the constructs. These two issues are briefly summarized in terms of their impact on the conceptualization of the perceived behavioral control construct.

A previous section discussed the differences in the conceptual definitions of both behavioral and normative beliefs as compared to the definition of control beliefs. In short, behavioral and normative beliefs are defined as the expectancy or likelihood
that performing a behavior results in a particular outcome and the expectancy or likelihood that a particular referent thinks that the individual should or should not perform the behavior, respectively. Control beliefs have been defined as a set of beliefs that "deals" with the presence or absence of resources and opportunities requisite for performing a given behavior (Ajzen and Madden, 1986; Ajzen, 1988). Unlike behavioral and normative beliefs that are specific in their description, i.e. phrased in terms of expectancy or likelihood, the definition of control beliefs is less specific in description.

Ajzen and Madden (1986) have published the only study to date that attempted to operationalize the set of control beliefs with belief-based measures of perceived behavioral control. However, this attempt merely adds confusion to the current conceptual definition of control beliefs. Specifically, the authors followed different approaches for operationalizing the beliefs for the two behaviors included in their study. For the first behavior under study, subjects rated their beliefs about the frequency in which ten factors (identified in a pilot study), might conflict with their performing a given behavior. Although all the pairs of anchors for the scales were not reported, they did report using "many events/none at all" and "never/frequently". Thus, it appears that for the belief-based measure developed to represent control beliefs pertaining to this behavior, the intention of the authors was to determine the frequency of occurrence of factors influencing control. For the second behavior that was studied, subjects were asked to respond to eight belief statements pertaining to facilitating or inhibiting factors (also identified in a pilot study) that might influence their performing the behavior. Again, all of the pairs of anchors were not reported but the authors did mention using "frequently/never" and
likely/unlikely". It is less clear in this case what Ajzen and Madden intended to determine with this belief-based measure of perceived behavioral control.

In terms of contributing information about the nature of the determinant or antecedent of the perceived behavioral control construct, Ajzen and Madden's (1986) attempt to operationalize the set of control beliefs generates confusion. That is, items included in the belief-based measures differed in terms of what they requested the subjects to rate. Furthermore, the scales on which the subjects responded varied between frequency and likelihood measures. The subtle difference between these two types of definitions have been discussed in terms of their conceptual differences, subsequent development of measures, and their implications for study results. Therefore, studying their approach for operationalizing this set of beliefs does not clarify, but rather clouds the conceptual definition of control beliefs.

In short, the issue of a conceptual definition of "control beliefs" raises two concerns. First, the definition, itself, is ambiguous in that the definitions for both behavioral and normative beliefs are specific whereas the definition of control beliefs is not specific. In addition, the approach taken to operationalize the set of control beliefs has not been consistent and thus, contributes little to the conceptual definition of control beliefs. Therefore, a definition of control beliefs that is conceptually clear and consistent is needed in order to further conceptualize the nature of these beliefs and operationalize the perceived behavioral control construct.

The second issue that needs to be discussed pertains to the difference between the conceptual definition of the perceived behavioral control construct and the conceptual definitions of both the attitude and subjective norm constructs. In the following discussion, the issue relating to the definition of control beliefs is ignored for the moment.
This investigation has previously proposed that the ability of a set of "control beliefs" to adequately encompass the entire concept of perceived behavioral control seems unlikely. In fact, it has been suggested that the conceptualization of this construct is too simplistic to contribute much to the explanation of complex human behavior. The bases for these propositions can be better explained and supported by considering the conceptualization of attitude and subjective norm, in terms of their antecedents.

The roles that salient behavioral and normative beliefs play in determining attitude and subjective norm, respectively, are significant. Specifically, an individual's expectancy or beliefs that performing a given behavior leads to 'n' consequences determines, in part, his attitude toward the behavior. Likewise, the individual's expectancy or beliefs that particular referents think that he should or should not perform the behavior determines, in part, his subjective norm. The piece that is missing at this point for both of these constructs, i.e. attitude and subjective norm, is an answer to: "So what if the individual holds these beliefs?" or "To what extent or how do these beliefs impact the individual's attitude or subjective norm?". The answers to these questions are currently provided by the conceptualization of both attitude and subjective norm.

In the case of behavioral beliefs, a belief that performing a given behavior leads to a certain consequence is limited in use unless it is known how the individual evaluates the consequence or outcome. For example, an individual may strongly believe that performing a given behavior will lead to an outcome that he evaluates very positively. Another individual may believe just as strongly that performing the behavior will lead to the same outcome but evaluates this outcome negatively. For simplicity, if one assumes that only one consequence results from performing the
behavior, the individual in the first situation will obviously have a positive attitude toward the behavior whereas the other individual's attitude will be negative. This example, therefore, demonstrates that a likelihood measure of belief provides only one component of the requisite information for assessing an individual's attitude toward the behavior. A similar example could be offered for the subjective norm construct.

For both attitude and subjective norm, then, two requisite pieces of information are contained in the constructs' definitions, providing a more complete picture of each construct's conceptual meaning. These pieces, or components, are multiplicatively combined in the composites underlying these constructs. Specifically, an expectancy-value composite consisting of the likelihood of salient behavioral beliefs multiplied by the corresponding evaluation of these beliefs' outcomes underlies or determines attitude; and a normative belief-motivation to comply composite consisting of the likelihood of normative beliefs multiplied by the corresponding motivation to comply with the normative referents underlies or determines subjective norm.

In terms of perceived behavioral control, this investigation proposes that its conceptual picture is presently less complete than the conceptual pictures of attitude and subjective norm. Specifically, the component consisting of salient control beliefs is addressed but the effect or impact of these beliefs on the individual's perception of behavioral control is ignored. This investigation suggests that similar to the conceptualization of attitude and subjective norm, perceived behavioral control also needs to address: "So what if the individual holds beliefs about factors that may influence or control the individual's performance of the behavior?" or "To
what extent or how these beliefs impact the individual's perception of behavioral control?".

To summarize the discussion to this point, this investigation raises two issues that have not yet been addressed in currently published research but are critical to the conceptual development of perceived behavioral control and its antecedent: (1) the definition and nature of "control beliefs" and (2) the missing component that accounts for the impact or influence of these beliefs. The remainder of this section describes the approach developed in this investigation to address these two issues.

This investigation concurs with previous research in proposing that, similar to the sets of salient behavioral and normative beliefs that presumably underlie attitude and subjective norm, respectively, a set of salient "control beliefs" underlies perceived behavioral control. In addition, similar to the significant role that behavioral and normative beliefs play in determining attitude and subjective norm, respectively, this investigation proposes that the role that control beliefs play in determining perceived behavioral control is significant. However, different from previous conceptualization of perceived behavioral control, this investigation proposes that a control belief (CB) should be conceptualized and operationalized similar to behavioral and normative beliefs. Specifically, the definition of a control belief should consistently incorporate the term 'expectancy' or 'likelihood' rather than 'frequency' or a mixture of the 'likelihood' and 'frequency'. Furthermore, the nature of these control beliefs needs to be conceptualized and clearly stated. These steps should help improve the reliability of the belief-based measures, thus providing more "true" path estimates. The present investigation addresses this concern by taking another look at the definitions of control beliefs provided by Ajzen and his

As previously stated, Ajzen and his colleagues have consistently maintained that a set of beliefs about the availability of requisite resources and opportunities provide a basis for, or underlie an individual's perception of control over a given behavior. In addition, factors, either internal or external to the individual, are known as control factors and influence the degree of control an individual has over performing a behavior. Although Ajzen has not explicitly explained the relationship between resources/opportunities and internal/external factors, this investigation views resources (e.g. ability) as similar to factors that are internal to the individual, and opportunities (e.g. time) as similar to factors that are external to the individual (Anon., 1985). This view is reflected, hereafter, in defining control beliefs as a set of beliefs about the availability of control factors, both internal and external to the individual, that are requisite to performing the behavior under study. While the term "availability" may be appropriate for use with some factors, particularly with external control factors (i.e. time, assistance, etc.), it seems semantically inappropriate when referring to factors that are internal to the individual, such as skills, ability, knowledge, etc. This study proposes that appropriate terms to describe the "availability" of these factors include: "presence" of skills, "have" the skills, "possess" the skills, etc.

This investigation defines a control belief (CB), then, as the expectancy or likelihood that a factor that influences an individual's control over performing a given behavior will be "available", will be "present", or that the individual will "possess", will "have", etc. The difference between this study's definition of a control belief and Ajzen his colleagues' definition is important to understand. First,
although Ajzen and his colleagues have defined control beliefs as a set of beliefs about the availability of resources and opportunities requisite for performing the behavior, the nature of their belief-based items have focused on the occurrence of the control factors rather than the availability or possession of them. Second, in operationalizing control beliefs based on their definition, Ajzen and Madden (1986) have focused on both the frequency and the likelihood of the control factor's occurrence rather than on one or the other. The definition of control beliefs proposed in this investigation appears to reflect the meaning provided by Ajzen and his associates more closely than their attempts to operationalize the set of beliefs reflect.

In conceptualizing and operationalizing control beliefs, this investigation recognizes that an individual may respond similarly to scales posed in terms of frequency or likelihood. However, for reasons discussed earlier, it is advantageous to select one scale over the other. The "likelihood" scale is selected over the "frequency" scale for several reasons. First, consistency among the definitions of behavioral, normative, and control beliefs is desirable in terms of the development of measures. By developing belief items and anchoring belief scales similarly, it is anticipated that the measurement instrument will be more standardized, thereby contributing to the instrument's validity and reliability. Second, it seems more reasonable to conceptualize beliefs about control factors in terms of their likelihood of availability or possession rather than their frequency of availability. In addition, it is proposed that the concept of likelihood provides the information needed both to reflect "control beliefs", as described by Ajzen, and to understand the perceived behavioral control construct. Specifically, it seems more valuable from a research perspective to determine if an individual expects a factor to be available or possessed
rather than if he can report how frequently or often it is available. For example, requesting an individual to estimate the likelihood of having the skills to perform behavior 'X' seems valid whereas asking him to estimate the frequency that he has the skills to perform the same behavior is nonsensical.

At this point, then, the conceptualization of perceived behavioral control includes one of the requisite pieces of information to provide the construct's complete conceptual picture as proposed in this investigation, i.e. the definition and nature of "control beliefs". The second component of information is still missing: "To what extent or in what way do these beliefs impact the individual's perception of control? and "So what if the individual holds these beliefs". Although it is important to determine how likely a control factor is available or possessed by the individual, the use of this information is limited if the extent to which it influences, or how it influences, or the effects of its influence is unknown. In answering these questions, this investigation proposes that two characteristics of influential behavior are important to determine: (1) the direction of influence, and (2) the magnitude of influence.

To determine an appropriate approach for incorporating the direction and magnitude of a behavior's influence on an individual's perception of control, briefly reexamining the definition of perceived behavioral control and control beliefs provides some guidance. In the work conducted by Ajzen and his colleagues, the influence of control factors on behavior has been described as either facilitating or inhibiting (Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1987; Ajzen, 1988; Beck and Ajzen, 1991). This investigation proposes that the direction and magnitude of control factors' influence, or the strength of their influence (SI), can be represented on a scale ranging from 'facilitate' to 'prevent'. Determining a
control factor's position on this scale, i.e. a measure of a control factor's strength, would answer the questions pertaining to: (1) "To what extent or how does the control factor's availability or possession influence the individual's performance of the behavior", and (2) "So what if the individual holds these control beliefs?".

For example, one factor that is external to the physician but may influence his reporting a serious adverse drug event to the FDA is the availability of time for performing the behavior. The control belief corresponding to this factor can be proposed as: "When the next serious ADE occurs in my practice, I will have the time to report it to the FDA ... likely/unlikely. Although this piece of information is important to know, knowing this piece solely can lead to an erroneous conclusion. In this case, if the physician responds that it is extremely unlikely that he will have the requisite time, this 'piece' of knowledge, by itself, may suggest that he will not complete and submit the reporting form. However, if the physician expects to lack the time needed to submit the report but the hospital in which he staffs requires him to perform this behavior, his belief about the control factor, i.e. not having the available time, may not adequately reflect his actual performance of the behavior. In another example, if the physician expects to lack the time but the lack of time is less inhibiting than the effect from other control factors, the influence of this control belief on his intentions and behavior may be less significant than the influence of other salient control beliefs.

These examples support the need to include both the salient control beliefs and the strength of their influence as determinants of perceived behavioral control. One component, i.e. the control beliefs, addresses the likelihood that the factors that potentially influence the individual's performance, are available or possessed. The other component, i.e. strength of influence, addresses the direction and magnitude
of the influence of these control factors, thereby answering the question: "to what extent or in what way does the control factor's availability or possession influence the individual's performance of the behavior?"

Therefore, this investigation proposes, that similar to attitude and subjective norm, the antecedent of perceived behavioral control is a composite. This composite consists of: (1) the individual's control beliefs ($CB_k$), i.e., the beliefs that salient control factors are available to or possessed by the individual, and (2) the individual's estimate of the strength of influence ($SI_k$) these control beliefs have on his performing the behavior. Each control belief ($CB$) is multiplied by its strength of influence ($SI$) and the products are summed to produce the control belief-strength of influence (CBSI) composite as depicted in Equation 2.4.

$$PBC = \sum_{k=1}^{n} CB_k SI_k$$

(Eq. 2.4)

The CBSI composite proposed to underlie and determine perceived behavioral control differs from the belief-based concept developed and measured in Ajzen and Madden's (1986) study in several ways. First, the composite includes a belief component that addresses the individual's belief or expectancy that factors requisite for performing a given behavior are available or possessed by the individual. On the other hand, the belief-based determinant seems to address the individual's belief about the frequency of occurrence of factors that could prevent or facilitate
behavioral performance. The belief component of the composite matches the description of control beliefs that is provided by Ajzen and further conceptualized in this investigation more closely than the belief-based concept. Second, the composite includes a component that addresses how, in terms of direction and magnitude, the availability or possession of control factors influences the individual's perception of control over performing the behavior. However, the belief-based concept identifies all salient factors, either inhibiting or facilitating, that influences the individual's perception of control. Therefore, it appears that the belief-based concept assumes invariant influence by control factors, in terms of strength and direction of influence.

To compare and test the differences between the conceptual approaches proposed in this investigation and the one provided by Ajzen and his colleagues, diagrammatic representations are necessary. The illustration of 'control beliefs' as underlying, or determining, perceived behavioral control has not been provided by Ajzen and his associates (Ajzen, 1985; Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1987; Ajzen, 1988; Beck and Ajzen, 1991). This investigation suggests, therefore, that this set of beliefs be represented as the construct 'Control Belief' (see Figure 6, Panel A). The individual control beliefs (C) are measures, or indicators, of this construct and this construct (CB) is the antecedent of perceived behavioral control.

The antecedent of perceived behavioral control proposed in this investigation exists as a composite and is illustrated in Figure 6, Panel B. The composite consists of: (1) one component that addresses the beliefs (CB) about the availability or possession of factors that influence the control the physician has over reporting a serious adverse drug event to the FDA, and (2) one component the addresses the
Panel A: Control Belief (CB) as Antecedent

Panel B: Control Belief-Strength of Influence (CBSI) as Antecedent

Figure 6: Antecedent of Perceived Behavioral Control
strength of influence (SI), in terms of direction and magnitude, of these factors on the physician's control over reporting.

Although at least one of the belief-based measures used in Ajzen and Madden's (1986) study was a mixture of frequency and likelihood measures, this investigation uses control beliefs (C) defined and measure only as likelihood items as the determinant of the construct 'Control Belief'. As previously explained, mixing the types of scales within one measure may decrease the reliability and validity of the scale. Therefore, the use of a measure including only likelihood items should be a more rigorous test of any difference between a belief-based representation (CB) of perceived behavioral control and a control belief-strength of influence (CBSI) representation. The specified proposition is tested in Hypothesis 3.1.

**Hypothesis 3.1:**

H3.1: An antecedent of perceived behavioral control that is represented as a control belief-strength of influence (CBSI) composite will provide a significant improvement in fit to the data over an antecedent that is represented as a component consisting only of control beliefs (CB).

Before proceeding to the next section, one additional issue needs to be briefly discussed. Unknown at the time that this investigation was proposed and developed, Ajzen (1991, in press) has recently taken a seemingly similar approach to conceptualize perceived behavioral control. Specifically, Ajzen (p. 18) proposes that a composite underlies perceived behavioral control in which "each control belief (c) is multiplied by the perceived power (p) of the particular control factor to facilitate or inhibit performance of the behavior, and the resulting products are summed across the n salient control beliefs to produce the perception of perceived
behavioral control. While the approaches appear to be quite similar, it is unclear at this time how 'control belief' and 'power' are defined and operationalized. Specifically, Ajzen continues to describe control beliefs as "a set that deals with the presence or absence of requisite resources and opportunities" and does not define 'power'. Whether or not a control belief is a belief about the frequency or likelihood of control factors occurring is not addressed. Furthermore, whether or not "power" is operationalized to account for variations in "power" across individuals and between "control factors" is not addressed. In the brief discussion of this approach, Ajzen cites an unpublished study (Ajzen and Driver, 1990) that used this composite to measure perceived behavioral control with respect to several leisure activities, such as jogging, boating, etc. However, since this study's operationalization and measurement of 'control beliefs' and 'power' are not discussed, the overlap between this investigation's and Ajzen's conceptualization of perceived behavioral control is not known.

Structure of Antecedent of Perceived Behavioral Control

Proceeding with the conceptualization of perceived behavioral control, another objective of this research is to examine the structure of this construct's antecedent. This objective is addressed in Research Question 4 and the development of Hypotheses 4.1 and 4.2.

Research question 4. What is the structure, or underlying dimensional nature, of the antecedent of perceived behavioral control? Does the antecedent of perceived behavioral control support a two-dimensional representation such as that found with
expectancy-value attitude and the normative belief-motivation to comply composite within the Theory of Reasoned Action?

**Development of hypotheses.** The dimensionality of the antecedent of perceived behavioral control has not been examined to date. Since only one study has measured the beliefs about behavioral control via incorporating a belief-based PBC measure, the opportunity to address the issue of dimensionality has been relatively nonexistent. Ajzen and Madden (1986) used confirmatory factor analysis to address the dimensionality of their direct measures of perceived behavioral control. In terms of their belief-based measures, confirmatory factor analysis was used to identify a subset of bipolar adjectives that represented one evaluative dimension for each behavior under study rather than to identify dimensions underlying control beliefs.

The absence of any research pertaining to a multidimensional representation of the antecedent of perceived behavioral control is no surprise. First and foremost, Ajzen and his colleagues, who have conducted the most research of the perceived behavioral control construct and the Theory of Planned Behavior, assume that the construct is unidimensional, in nature. Thus, their research has not looked or tested for a multidimensional representation of perceived behavioral control. Reasoned Action or the Theory of Planned Behavior. Second, the conceptualization of the antecedent of perceived behavioral control has been relatively limited and thus, examining the structure underlying this antecedent by other investigators is of lower priority.

Other researchers have found support for the multidimensional structure of expectancy-value attitude and the normative belief-motivation to comply composite within the Theory of Reasoned Action. This investigation intends to test the
dimensional nature of expectancy-value attitude and the normative belief-motivation to comply composite within the Theory of Planned Behavior. This study has also proposed a conceptual representation of the antecedent of perceived behavioral control that may lend itself to a multidimensional representation. Therefore, it seems reasonable to consider the issue of dimensionality with the antecedent of perceived behavioral control proposed in this investigation.

In the previous section, this investigation proposed that a CBSI composite is the antecedent of the perceived behavioral control construct. This composite is proposed to consist of a belief component (CB) and a component addressing the strength of influence (SI) of the control factors on perceptions of behavioral control. In terms of the underlying dimensional structure of the CBSI composite, previous research with the perceived behavioral control was examined to assist in proposing the possible number and nature of dimensions.

A review of research by Ajzen and his colleagues suggests that two possible pairs of dimensions exist: (1) facilitating and obstructing or inhibiting control factors, and (2) internal and external control factors (Ajzen 1985; Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1987; Ajzen, 1988). In terms of facilitating and obstructing factors, Ajzen and Madden (1986, pp. 462, 466) conducted a pilot study for each behavior under study and elicited "factors that could prevent" (attending class) and "factors that might help or prevent" (getting an 'A'). If "control beliefs", as described and operationalized by Ajzen and Madden, were the only determinant of perceived behavioral control, it would seem reasonable to propose "facilitating" and "obstructing/inhibiting" factors as the two dimensions. However, this investigation has proposed that the composite underlying perceived behavioral control accounts for the facilitating or inhibiting influence of a factor on
an individual control over performing a behavior via the "strength of influence" (SI) component. The use of the entire range of a factor's influence over performing a given behavior, as is provided by this composite, is more desirable than specifying two dimensions that describe the two extremes of this influence, i.e. "facilitating" and "obstructing".

The other possible pair of dimensions, i.e. internal and external control factors, are the dimensions proposed in this investigation. Since the introduction of the Theory of Planned Behavior, Ajzen and his colleagues have maintained that factors, both internal and external to the individual, can influence an individual's control over performing a given behavior (Ajzen, 1985; Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1987; Ajzen, 1988; Beck and Ajzen, 1991). These factors, previously defined as "control factors", have been discussed throughout this chapter.

Prior research with physicians' reporting intentions or behavior has indicated that reporting to the FDA might be influenced by both internal and external control factors, including: endless forms, the severity of the adverse drug event which influences their motivation, the documentation status of the adverse drug event, limitations in time, personal liability, inconvenience associated with reporting, and unavailability of the report form (Koch-Weser et. al., 1969; Griffin, 1984; Milstien et. al., 1986; Rogers et. al., 1988; Juergens, 1990). The control factors found to be salient in this investigation included: (1) obligation, (2) motivation, (3) time, (4) reporting forms, and (5) reporting assistance. 'Ability' was not identified as a salient factor in the exploratory study but related terms (e.g. training, organization skills) were mentioned by some physicians. In addition, 'ability' is one of the internal factors commonly cited by Ajzen and his associates (Ajzen, 1985; Schifter
and Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1987; Ajzen, 1988; Beck and Ajzen, 1991). Therefore, it seems reasonable to propose that the control factors identified in this investigation belong to one of two groups: (1) a group representing 'internal' control factors, and a (2) a group representing 'external' control factors. The 'internal' control factors include ability, motivation, and 'obligation' whereas the 'external' control factors include time, reporting form, and reporting assistance.

This investigation proposes, then, that similar to the multidimensional structure proposed for expectancy-value attitude and the normative belief-motivation to comply composite, the CBSI composite underlying perceived behavioral control is better represented by a two-dimensional than a unidimensional structure. This proposed two-dimensional structure includes one dimension that represents "internal" control factors and a second dimension that represents "external" control factors.

Following the theoretical approach presented with expectancy-value attitude and the normative belief-motivation to comply composite, the two-dimensional structure of the control belief-strength of influence composite is supported with the network representation of memory. Within the node of memory that represents the act of reporting a serious adverse drug event to the FDA, this investigation suggests that the linkages among internal control factors and among external control factors are stronger than between internal and external control factors. For example, it is reasonable to suggest that 'internal' factors are ones more personal to the physician and perhaps reflective, at least in his mind, of his personal and professional responsibility. In addition, it is reasonable to hypothesize that 'external' factors are perceived as factors beyond the physician's realm of control and the responsibility of someone else, such as the FDA, the hospital, the health care industry, society, etc.
Therefore, it is reasonable to propose that linkages are stronger in memory between the 'internal' control factors and between the 'external' control factors than between 'internal' and 'external' control factors.

One internal control factor identified as salient in the pilot study that may be problematic is 'motivation'. The problems lies in its potential overlap with the behavioral and normative beliefs that determine the motivation, or intention, to report serious adverse drug events to the FDA. This factor was retained and incorporated into a 'control belief' because Ajzen's (1986, p. 26) example of "power of will" and "strength of character" as an internal control factor seems motivational in nature. In addition, Ajzen and Madden's (1986, p. 467) use of "the extent to which the subject matter of the course stimulates motivation" as a control factor seems related to this investigation's use. That is, the issue of interest in this investigation is whether or not a serious adverse drug event would stimulate the physician's motivation to report it to the FDA. This may also be interpreted as whether or not the severe nature of the adverse drug event stimulated the physician's motivation to report it to the FDA. Therefore, "motivation" is proposed as an 'internal control factor'. However, this investigation examines its overlap with the motivational determinants of intention.

In summary, this investigation proposes that the control belief-strength of influence composite underlying perceived behavioral control is better represented by a two-dimensional rather than a unidimensional structure (See Figure 7). In addition, it is proposed that one dimension represents 'internal' control factors and the second dimension represents 'external' control factors. These propositions are tested in Hypothesis 4.1.
Panel A: Unidimensional CBSI

Obligation → CBSI
Motivation → CBSI
Ability → CBSI
Time → CBSI
Accessible Forms → CBSI
Reporting Assistance → CBSI

GC1 → PBC
GC2 → PBC
GC3 → PBC
GC4 → PBC

I1 → BI
I2 → BI

Panel B: Multidimensional CBSI: Internal and External Control Factors

Obligation → CBSII
Motivation → CBSII
Ability → CBSII
Time → CBSII
Accessible Forms → CBSII
Reporting Assistance → CBSII

GC1 → PBC
GC2 → PBC
GC3 → PBC
GC4 → PBC

I1 → BI
I2 → BI

Figure 7: Dimensionality of CBSI Composite
Hypothesis 4.1:

H4.1: A two-dimensional model of the control belief-strength of influence (CBSI) composite in which one dimension represents 'internal control factors' and the other represents 'external control factors' will provide a significant improvement in fit to the data over a unidimensional representation of the CBSI composite.

This investigation also proposes that a two-dimensional structure of the antecedent of perceived behavioral control would exist even if the set of 'control beliefs' (CB), as proposed by Ajzen and illustrated in Figure 8, was the determinant of the construct. In addition, similar to the previous hypothesis, this investigation proposes that one dimension would represent 'internal control factors' and the second dimension would represent 'external control factors' (See Figure 8).

Hypothesis 4.2

H4.2: A two-dimensional model of the control belief (CB) construct in which one dimension represents 'internal control factors' and the other represents 'external control factors' will provide a significant improvement in fit to the data over a unidimensional representation of the CB construct.

The Role of Perceived Behavioral Control

The two preceding research questions would not be needed if examining the role of perceived behavioral control was not an objective of this investigation. The question and hypothesis needed to address this objective are included in Research Question 5 and Hypothesis 5.1.
Panel A: Unidimensional CB

Obligation
Motivation
Ability
Time
Accessible Forms
Reporting Assistance

Panel B: Multidimensional CB: Internal and External Control Factors

Obligation
Motivation
Ability
Time
Accessible Forms
Reporting Assistance

Figure 8: Dimensionality of CB Construct
Research question 5. Does perceived behavioral control have an impact on behavioral intentions when added to the Theory of Reasoned Action, i.e. is the Theory of Planned Behavior a more adequate model for predicting physicians' reporting intentions than the Theory of Reasoned Action?

Development of hypothesis. An earlier section discussed the reasons why the Theory of Planned was selected over the Theory of Reasoned Action as the behavioral model on which to base this investigation's model. Specifically, previous research has suggested that physicians' reporting behavior may not be completely volitional in nature. That is, factors that are both internal and external to the physician, may influence whether or not he can complete and submit the reporting form to the FDA. The nature and number of these factors have been previously described.

Based on the review of literature and the theoretical support provided throughout this chapter, the concept of perceived behavioral control is viewed as an integral component in the prediction of physicians' intention to report serious adverse drug events to the FDA. Therefore, the Theory of Planned Behavior is proposed to be a more adequate model for prediction than the Theory of Reasoned Action in this investigation (see Figure 9). This proposition is tested in Hypothesis 5.1.

Hypothesis 5.1

H5.1: The Theory of Planned Behavior will provide a significant improvement in fit to the data over the Theory of Reasoned Action.
Panel A: Theory of Reasoned Action (TRA)

Panel B: Theory of Planned Behavior (TPB)

Figure 9*: Models for Research Question 5

* For diagrammatic simplicity, the proposed correlations between all determinants of BI are omitted.
Past Behavior and the Theory of Planned Behavior

One objective of this research is to determine the role of past behavior in the Theory of Planned Behavior. This objective involves addressing several research questions and hypotheses. The questions and hypotheses needed to address this objective are included in Research Question 6 and Hypotheses 6.1, 6.2.1, 6.2.2, and 6.3.

Research question 6. What are the determinants of past behavior? Does past behavior have an independent effect on intentions or attitudes within the Theory of Planned Behavior? To what extent does past behavior overlap with the perceived behavioral control construct?

Development of hypotheses. In examining the role of past behavior in a model proposed to be similar to the Theory of Planned Behavior, Bagozzi and Warshaw (1990) found that both the frequency and recency of past behavior influenced behavioral intention and behavior. In short, the frequency of past behavior was proposed to directly impact intentions because attitudes were based on partially self-generated inferences rather than perfect reflections of past behavior and thus, did not mediate all of the effects of past behavior. The recency of past behavior was proposed to directly impact behavior because bias from recency heuristics would create differences between intentions (that were biased) and actually performing the behavior (that was not biased). Other effects of the recency of past behavior on components in the model were proposed to be mediated through the 'frequency' determinant. Study results supported the independent effects of both the frequency of past behavior on intention and the recency of past behavior on behavior. Because
the authors proposed that any effect of the recency of past behavior on components in the model other than behavior would be mediated by 'frequency', testing a direct effect of 'recency' on intentions was not reported.

Most of the studies that have included a measure of past behavior in their behavioral intention models have included 'frequency' as the only measured variable, or indicator. Based on Bagozzi and Warshaw's (1990) work, this investigation proposes that both recency and frequency are significant indicators of past behavior. However, their effect on behavioral intentions is proposed to be mediated by a construct representing past behavior (PB). Similar to the findings of Bagozzi and Warshaw, this study also proposes that these indicators are highly associated or correlated. Since this investigation does not include a measure of behavior, the propositions stated above are relevant to only behavioral intention. The proposition to be tested, therefore, is provided in Hypotheses 6.1.

**Hypothesis 6.1**

H6.1: Both frequency (F) and recency (R) are significant indicators of physicians' past reporting of serious adverse drug events to the FDA.

Previous sections pertaining to the perceived behavioral control construct have discussed the potential role that past behavior plays in the Theory of Reasoned Action. Studies with this theory have supported the effect of past behavior on behavioral intention and behavior. In addition, some evidence has been provided indicating that past behavior also directly influences attitude.

The potential role that past behavior plays in the Theory of Planned Behavior has also been discussed. One major concern with respect to this issue is the conceptual
overlap of past behavior with the concept of perceived behavioral control. In terms of empirical support, one study found that perceived behavioral control had a significant effect on intentions above and beyond any effect of past behavior, thus indicating that perceived behavioral control is conceptually distinct from past behavior (Ajzen and Madden, 1986). However, the effect of past behavior above and beyond any effect of perceived behavioral control was either not conducted or not reported. In another study of three behaviors, past behavior was found to be a significant predictor of behavioral intention above and beyond any effect from perceived behavioral control.

Beck and Ajzen (1991) contend that any effect of past behavior on intentions and behavior is an issue of the model's sufficiency. Specifically, they claim that if past behavior appears to have a significant effect beyond the effect of predictor variables included in the model, then all factors that determine behavior have not been identified.

This investigation proposes to test the 'sufficiency' of the Theory of Planned Behavior and the conceptual overlap between past behavior and the perceived behavioral control concept. Specifically, two sets of models will be compared: (1) the Theory of Planned Behavior versus a modified-Theory of Planned Behavior in which past behavior is included as the fourth determinant of behavioral intention (MTPB-1), and (2) a modified-Theory of Reasoned Action in which past behavior is included as the third determinant of behavioral intention (MTRA-1) versus MTPB-1. These models are illustrated in Figure 10, Panels A through D.

The first comparison addresses two issues: (1) the direct impact of past behavior on behavioral intentions, and (2) the direct impact of past behavior on attitudes. Both issues combine to address the much larger issue: whether or not past behavior
Panel A: Theory of Planned Behavior (TPB)

ATT → BI
GSN → BI
PBC → BI

Panel B: Modified Theory of Planned Behavior (MTPB-1)

ATT → PB → BI
GSN → BI
PBC → BI

Panel C: Modified Theory of Planned Behavior (MTPB-1a)

ATT → PB → BI
GSN → BI
PBC → BI

Panel D: Modified Theory of Reasoned Action (MTRA-1)

ATT → PB → BI
GSN → BI

Figure 10*: Models for Research Question 6

* For diagrammatic simplicity, the proposed correlations between all determinants of BI are omitted.
directly affects behavioral intentions, thus indicating whether or not the Theory of Planned Behavior is a sufficient model.

Based on the relatively significant amount of research with both the Theory of Reasoned Action and the Theory of Planned Behavior that has supported the PB-\(\rightarrow\)BI pathway, this investigation proposes that physicians' past behavior will have a significant and independent effect on their intentions to report serious adverse drug events to the FDA (See Figure 10, Panels A and B). Hypothesis 6.2.1 provides the test of this proposition.

**Hypothesis 6.2.1**

H6.2.1: A modified model of the Theory of Planned Behavior in which past behavior directly impacts behavioral intention (MTPB-1) will provide a significant improvement in fit to the data over the Theory of Planned Behavior (TPB).

Compared to the extent of literature that supports the PB-\(\rightarrow\)BI pathway, less support has been found for past behavior's direct impact on attitude. The support that has been provided has been in tests of the Theory of Reasoned Action. The lack of support may be due to minimal research examining this pathway with both the Theory of Reasoned Action and the Theory of Planned Behavior. This investigation contends that the test of this pathway is important. However, it proposes that past behavior does not directly impact attitude or subjective norm, rather its effects on these constructs are mediated by expectancy-value attitude and the normative belief-motivation to comply composite. This proposition is concordant with the assumptions underlying the Theory of Reasoned Action and the Theory of Planned Behavior. Figure 10, Panel B (MTPB-1) and Panel C (MTPB-1a) illustrate the
models to be compared and Hypothesis 6.2.2 states the test of the proposition described above.

Hypothesis 6.2.2

H6.2.2: A modified model of the Theory of Planned Behavior in which past behavior directly impacts attitude and behavioral intention (MTPB-1a) will not provide a significant improvement in fit to the data over the modified model in which past behavior directly impacts only behavioral intention (MTPB-1).

To test the conceptual overlap between past behavior and perceived behavioral control, a comparison similar to the one conducted by Ajzen and Madden (1986) is proposed. Specifically, two models are compared: one in which the Theory of Reasoned Action is modified by including past behavior (MTRA-1) and one in which the Theory of Planned Behavior is modified by including past behavior (MTPB-1). The comparison of these two models will indicate whether or not perceived behavioral control has an effect on behavioral intention after accounting for any effect from past behavior (see Figure 10, Panels B and D).

Based on the research conducted with the Theory of Planned Behavior, this investigation proposes that physicians' perception of control over reporting to the FDA has a significant impact on their intentions to report that is above and beyond any effect on intention by their past behavior. That is, this study proposes physicians' perceived behavioral control is not merely a reflection of their past reporting behavior. Hypothesis 6.3 provides the test of this proposition.
Hypothesis 6.3

H6.3: A modified model of the Theory of Planned Behavior in which past behavior directly impacts behavioral intention (MTPB-1) will provide a significant improvement in fit to the data over the modified model of the Theory of Reasoned Action in which past behavior directly impacts behavioral intention (MTRA-1).

Other Model Issues

One issue pertaining specifically to the development of this investigation's model became apparent during the exploratory study. While eliciting salient beliefs from physicians about the consequences of reporting adverse drug events to the FDA, two categories of beliefs emerged: (1) beliefs about the consequences of reporting an adverse drug event to the FDA and (2) beliefs specifically about the FDA. Many physicians had strong beliefs about characteristics of, if not biases toward, the FDA. Some of these beliefs were targeted at the bureaucratic and inefficient nature of the FDA, as a government agency. Because physicians' beliefs about the FDA were sometimes incongruent with their beliefs about reporting adverse drug events, it seemed reasonable to examine physicians' attitude toward the FDA, i.e. attitude toward an object, as a predictor of their intentions to spontaneously report adverse drug events to the FDA. The role that this issue plays in developing the behavioral intention model in this investigation is addressed in Research Question 7 and Hypotheses 7.1, 7.2, and 7.3.

Research question 7. Do physicians' attitudes toward the FDA, i.e. attitude toward an object (ATT_o), have any effect on their intentions that is independent of
their attitude, subjective norm, and perceived behavioral control with respect to the act of reporting adverse drug events to the FDA?

**Development of hypotheses.** The Theory of Planned Behavior, as well as the Theory of Reasoned Action, include 'attitude toward the behavior' as a predictor, or determinant, of behavioral intention. The majority of research in the psychology and consumer behavior literatures supports the use of attitude toward a behavior (ATT) over the use of attitude toward an object (ATT₀) because the latter has demonstrated limitations in explicative and predictive usefulness. Some support, however, has been offered for the use of attitude toward an object when it is used within the context of a situation (Rokeach, 1972).

This investigation proposes that both attitude toward the behavior of reporting to the FDA and attitude toward the FDA as an object may influence physicians' intention to perform the behavior. That is, this study suggests that physicians can hold two sets of beliefs that are relatively independent but are also associated to some extent. Furthermore, this study proposes that these beliefs determine two independent but correlated attitudes that may influence the formation of physicians' intentions to report to the FDA. These two sets of beliefs include: (1) beliefs about the act of reporting a serious adverse drug event to the FDA, and (2) beliefs about the FDA as an object, agency, or an organization. According to the Theory of Planned Behavior, the first set of beliefs underly physicians' attitude toward reporting to the FDA. The second set of beliefs underly physicians' attitude toward the FDA, an attitude that is proposed in this study to be very much different from their attitude toward reporting adverse drug events.
The theoretical support for this proposition returns to the research in information processing pertaining to the network association of memory. Specifically, this investigation proposes that reporting an adverse drug event to the FDA can be represented as a node in physicians' memory. This node supports a network of associations in which objects, ideas, individuals, etc. pertaining to spontaneous reporting to the FDA are linked together based on physicians' learning experiences. In addition, it is proposed that another node exists in physicians' memory that specifically pertains to the FDA as an organization, government agency, object, etc.

This study proposes two separate nodes because: (1) reporting adverse drug events to the FDA is not an activity limited to the FDA, i.e. reports can be sent to other interested agencies such as specialized registries, pharmaceutical manufacturers, etc. and (2) the FDA plays a great number of roles in physicians' practices in addition to its role as a recipient of adverse drug events and thus, and stimulates many perceptions in providers. Therefore, while the behavior (i.e. reporting to the FDA) and the recipient of the behavior (i.e. the FDA) are proposed to be represented by different nodes, it is reasonable to suggest that associations, or linkages, some of which may be relatively strong, exist between the two.

This study proposes that the activation of one node in memory may trigger or stimulate the activation of another node. In addition, it is suggested that the extent to which one node triggers the other node depends on the nodes' relative susceptibility to activation. That is, if one node is highly susceptible to stimulation, the deliberate activation of one node may trigger the activation of the more highly susceptible node. On the other hand, if the highly susceptible node is the one initially triggered, its activation may not trigger activity in the node that is relatively less susceptible. Accordingly, this study proposes that linkages between nodes may
support directional activation. Specifically, the stimulation of one node by another node to which it is linked may depend on the nodes' relative susceptibility toward activation. It is reasonable to suggest that the susceptibility of a node to activation may be related to characteristics of its network of associations or linkages. This investigation proposes that these characteristics may include the number or quantity of linkages within and exiting this node and the strength of these linkages.

The suggestion of directional activation between nodes can support the proposal of two or more categories of elicited beliefs during an exploratory study. For example, if the behavior under study is one in which strong beliefs are associated with the recipient of the behavior or an object used with performing the behavior, and these beliefs about the recipient or object have been developed in a context that is separate from the individual's performance of the behavior, activating the node representing the behavior may trigger the activation of the node representing the object. In this case, in addition to activating beliefs about performing the behavior, beliefs associated with the object may also be activated, thus resulting in the basis of two attitudes contributing to the prediction of behavioral performance. Simply put, activation of the node representing the object may not overshadow the output of the node representing the behavior, rather contribute independently to the behavior's prediction.

This investigation proposes, then, that attitudes can be stored relatively independently in memory but also overlap in that relatively strong linkages exist between the two. In addition, it is proposed that the susceptibility of nodes to activation can determine the direction and magnitude in which one node stimulates another. However, the activation of one node by another node may not entirely mediate the effects of the other activated node, rather both nodes may generate
beliefs, i.e. the basis of attitudes, that independently contribute to the prediction of a behavioral prediction. Although the Theory of Planned Behavior assumes that any impact attitude toward an object has on behavioral intention and subsequent behavior is mediated by the attitude toward the behavior, subjective norm or perceived behavioral control, the discussion provided in this section challenges this assumption.

In terms of physicians' intention to report adverse drug events to the FDA, this investigation proposes that the FDA represents a node in physicians' memory which is highly susceptible to activation. Due to the many roles of the FDA and the potential perceptions held by physicians, this study suggests that when the node representing the 'act of reporting to the FDA' is activated, this activation triggers the activation of the node representing the 'FDA as an agency'. The stimulation of this node generates many beliefs, attitudes, etc. that may be relatively unrelated to the 'act of the behavior' but also impact the formation of physicians' intention to report adverse drug events to the FDA. Therefore, this study proposes that attitudes toward the FDA is not entirely mediated by attitude, subjective norm, or perceived behavioral control with respect to reporting to the FDA.

At first glance, it may seem that this study could have chosen to represent the two sets of beliefs as different dimensions of physicians' attitude toward reporting adverse drug events to the FDA. However, this would have been an erroneous choice. Specifically, the construct 'attitude toward performing the behavior' should be based on beliefs pertaining to this construct, i.e. 'attitude toward the act'. Beliefs elicited about the FDA are obviously beliefs about an object and hence, should be the basis for the construct 'attitude toward the object'.
In summary, this investigation proposes that two attitudes held by physicians will have an independent but associated impact on physicians' intention to spontaneously report adverse drug events to the FDA: (1) their attitude toward reporting adverse drug events to the FDA (ATT), and (2) their attitude toward the FDA, an attitude toward an object (ATT_o). The two models to be compared in this proposition are illustrated in Figure 11, Panels A and B. This proposition is stated in Hypothesis 7.1.

Hypothesis 7.1

H7.1: A modified model of the Theory of Planned Behavior in which physicians' attitude toward the FDA directly impacts their intention to report adverse drug events to the FDA (MTPB-2) will provide a significant improvement in fit to the data over the Theory of Planned Behavior (TPB).

The previous hypothesis tests whether or not physicians' attitude toward the FDA impact their intention to report serious adverse drug events, above and beyond any effect on intentions by their ATT, GSN, and PBC. Two other hypotheses are necessary, however, to fully test the independent effect of attitude toward the FDA on physicians' intentions.

Research Question 6 proposed that the inclusion of past behavior in the Theory of Planned Behavior (MTPB-1) would provide a significant improvement in fit to the data over the Theory of Planned Behavior (TPB). In addressing this effect, Beck and Ajzen contend that if past behavior does have an effect beyond the effect of predictor variables included in the model, then all factors that determine behavior have not been identified. Since past behavior is included in the final model of
Panel A: Theory of Planned Behavior (TPB)

\[
\begin{align*}
\text{ATT} \quad & \quad \rightarrow \\
\text{GSN} \quad & \quad \rightarrow \\
\text{PBC} \quad & \quad \rightarrow \\
\end{align*}
\]

Panel B: Modified Theory of Planned Behavior (MTPB-2)

\[
\begin{align*}
\text{ATT} \quad & \quad \rightarrow \\
\text{GSN} \quad & \quad \rightarrow \\
\text{PBC} \quad & \quad \rightarrow \\
\end{align*}
\]

Figure 11*: Models for Research Question 7, Hypothesis 7.1

* For diagrammatic simplicity, the proposed correlations between all determinants of BI are omitted.
physicians' reporting intentions as an independent predictor, it is important to
determine if physicians' attitude toward the FDA is also an independent predictor,
i.e. above and beyond the effect of past behavior on intentions. It is also important
to determine if physicians' past behavior is an independent predictor of their
intentions to report, above and beyond any effect of attitude toward the FDA on
intentions. The models to be tested are illustrated in Figure 12, Panels A, B, and C
and the propositions are stated in Hypotheses 7.2 and 7.3.

Hypothesis 7.2

H7.2: A modified model of the Theory of Planned Behavior in which
both physicians' attitude toward the FDA and their past reporting
behavior impact their intention to report adverse drug events to the
FDA (MTPB-3) will provide a significant improvement in fit to the
data over the modified model of the Theory of Planned Behavior in
which physicians' past reporting behavior directly impacts behavioral
intention (MTPB-1).

Hypothesis 7.3

H7.3: A modified model of the Theory of Planned Behavior in which
both physicians' attitude toward the FDA and their past reporting
behavior impact their intention to report adverse drug events to the
FDA (MTPB-3) will provide a significant improvement in fit to the
data over the modified model of the Theory of Planned Behavior in
which physicians' attitude toward the FDA directly impacts
behavioral intention (MTPB-2).
Panel A: Modified Theory of Planned Behavior (MTPB-1)

Panel B: Modified Theory of Planned Behavior (MTPB-2)

Panel C: Modified Theory of Planned Behavior (MTPB-3)

Figure 12*: Models for Research Question 7, Hypotheses 7.2 and 7.3

* For diagrammatic simplicity, the proposed correlations between all determinants of BI are omitted.
A Model of Spontaneous Reporting Intentions

The previous discussion has presented seven research questions and several hypotheses to provide answers to these questions. To briefly summarize, the first research question has proposed that the expectancy-value attitude construct is two-dimensional rather unidimensional in structure. One dimension has been proposed to represent the positive consequences of reporting a serious adverse drug event to the FDA and the other to represent the negative consequences. The second research question has proposed that the normative belief-motivation to comply construct is also two-dimensional in nature in which one dimension represents 'authoritative' referents and the other dimension represents 'nonauthoritative' referents.

The third, fourth, and fifth research questions have addressed the antecedent of perceived behavioral control, the structure of this antecedent, and the role of perceived behavioral control in the Theory of Planned Behavior. Specifically, research question three has proposed that a composite of control beliefs-strength of influence (CBSI) provides a significant improvement in fit to the data over a construct consisting solely of control beliefs. Research question four has proposed that the structure underlying the CBSI composite is two-dimensional in which one dimension represents control factors that are 'internal' to the individual and the second dimension represents control factors that are 'external' to the individual. This underlying structure is also proposed to exist when the construct consisting solely of control beliefs is viewed as the antecedent of perceived behavioral control. Finally, the fifth research question has proposed that the Theory of Planned Behavior will provide a significant improvement in fit to the data over the Theory of Reasoned Action. Simply put, this question has addressed whether or not perceived
behavioral control plays a role in the formation of physicians' intentions to spontaneously report adverse drug events to the FDA.

The last two research questions have addressed the sufficiency of the Theory of Planned Behavior as a model for predicting physicians' reporting intentions. Research question six has proposed that physicians' past behavior will have an impact on their intentions to report that is independent from any effect that is mediated by the model's other constructs, i.e. attitude toward the behavior, subjective norm, and perceived behavioral control. In addition, this research question has further addressed the role of perceived behavioral control in the Theory of Planned Behavior by examining potential overlap between this construct and past behavior. Finally, the seventh research question has proposed that for the specific behavior under study in this investigation, physicians' attitudes toward the FDA may be sufficiently strong and independent from the model's other constructs to directly impact behavioral intention. Although the role of past behavior in the Theory of Planned Behavior has been tested, any role that attitude toward an object may play in this theory has not yet been examined.

In summary, the first four research questions and accompanying hypotheses intend to assist in developing 'submodels' for attitude toward the behavior, subjective norm, and perceived behavioral control that provide the most adequate fit to the study data, i.e. the most appropriate 'submodels'. After completing this accomplishment, attention is targeted at developing the most appropriate overall model for predicting physicians' reporting intentions. These efforts are undertaken in the last three research questions and their accompanying hypotheses. Based on the hypotheses developed in this section, then, the overall model proposed to most
adequately explain and predict physicians' spontaneous reporting intentions is illustrated in Figure 13.
Figure 13: Overall Model of Physicians' Spontaneous Reporting Intentions

*For diagrammatic simplicity, the proposed correlations between ATT, GSN, PBC, PB, and ATT₀ are omitted.
CHAPTER III
RESEARCH DESIGN AND PROCEDURE

This investigation included two studies: a relatively small-scale exploratory study and the primary investigation. First, the exploratory study's purpose, methodology, and results are presented. Second, the primary investigation's sampling procedure, development of the data collection instrument, and the data collection procedure are discussed. Third, the definition and measurement of the variables, evaluation of the questionnaire, and sources of error and bias are addressed. Finally, Chapter III discusses the data analysis, in terms of questionnaire response and analytical techniques used for the research hypotheses.

Exploratory Research

Purpose of Exploratory Research

In order to develop the primary investigation's data collection instrument, exploratory research was undertaken. Recommendations provided by Ajzen and Fishbein (1980, Appendix B) and research conducted by Burnkrant and Page (1988) and Ajzen and Madden (1986) guided the exploratory study's approach. The behavior under study in the exploratory research was physicians' spontaneous reporting of adverse drug events (ADEs), specifically to the FDA's spontaneous...
reporting system (SRS). Overall, there were three primary objectives important for developing valid measures of attitude, subjective norm, and perceived behavioral control. These include:

1. To identify salient beliefs about the consequences of spontaneously reporting ADEs to the FDA;

2. To identify salient referents who might have expectations about whether physicians should or should not spontaneously report to the FDA; and

3. To identify salient factors which might prevent or facilitate physicians' control over spontaneously reporting to the FDA.

Information pertaining to the frequency and recency of which physicians encountered and reported previous adverse drug events was also sought to assist in the development of a valid measure of past behavior.

Methodology of Exploratory Research

Sampling and Data Collection Procedure

Thirty to forty physicians were needed to complete a brief questionnaire designed to elicit salient beliefs about: the consequences of their spontaneous reporting (SR) behavior, referents, factors influencing their control over reporting adverse drug events, and information pertaining to the physician's past reporting behavior. Subjects for the exploratory study were randomly selected from the primary investigation's national sample (see Target Population and Sample Selection). Assuming an approximate 25% response rate, questionnaires for the exploratory study were mailed to 187 physicians. The exploratory questionnaire was
accompanied by a cover letter briefly describing the purpose of the questionnaire as well as the investigation. Subjects were encouraged to complete the survey and were assured that their responses would remain confidential.

Data collection instrument. The data collection instrument began with a brief introduction about adverse drug events, the FDA's definition of an ADE, and physicians' options for reporting them. Subjects were told that the study pertained specifically to their reporting of ADEs to the FDA via form 1639. Physicians were instructed to answer the survey's questions in terms of their participation in the FDA's SRS.

The instrument's first two questions asked subjects to list at least three advantages and then three disadvantages of their spontaneously reporting ADEs to the FDA. These questions were designed to elicit belief and evaluation statements required for operationalizing the expectancy-value composite of attitude toward the behavior (ATT). It was expected that physicians, busy with their patients and most likely disliking paperwork, may not respond at all to the survey or if they did, may only report their first thought pertaining to the question. Therefore, three responses per question were requested to encourage a more thorough elicitation. Next, subjects were asked to list at least three groups or individuals who may have expectations about whether or not they should report ADEs to the FDA. The following two questions addressed factors potentially influencing physicians' control over spontaneously reporting to the FDA. Specifically, physicians were asked to first list at least three internal and three external factors which may prevent or impair their reporting ADEs via 1639 form and then list three internal and external factors which may facilitate or improve their reporting.
For the five elicitation questions, brief definitions and examples were given where appropriate. The examples focused on the behavior of physicians participating on a hospital's Pharmacy and Therapeutics (P&T) committee. In the case of internal and external factors, generic examples such as "skills" (internal) and "availability of specific items necessary for your control" (external) were included in the definition.

The instrument's sixth question asked subjects if they were previously aware that the FDA maintains a spontaneous reporting system in which physicians submit written documentation of ADEs. Finally, the survey's last two questions requested subjects to indicate the likelihood that they would accurately remember both the number of ADEs encountered and when the last ADE occurred for several time periods.

The data collection instrument was evaluated by faculty who were very familiar with the design of elicitation surveys as recommended by Ajzen and Fishbein (1980). The final exploratory instrument was pretested with three locally practicing physicians. The pretest's purpose was to evaluate the clarity of the instructions and the questions, as well as assess the survey's completion time. Results of the pretest indicated one necessary change in spelling and a reasonably short completion time. The final data collection instrument used in the exploratory study is presented in Appendix A.
Results of Exploratory Research

Respondents

The response rate for the exploratory study's surveys was disappointingly low. Out of 187 mailed surveys, ten usable questionnaires were returned, netting a 5.3% response rate. Nine surveys were returned unopened because of incorrect addresses and one was returned partially complete. Three other questionnaires were returned incomplete because: (1) a pathologist did not feel qualified to respond to the survey's questions, (2) the physician had been retired for 4 years, and (3) the physician was out of the country.

One possible reason for the pretest's poor response rate is the type of questions included on the data collection instrument. Although the instrument was brief in length, consisting of only eight questions, the majority of questions were elicitative in design and subjects needed to think of and write answers rather than circle or check a provided response. The one survey returned partially complete had the elicitation questions marked out and the final three questions (check and circle responses) completed. This suggests that elicitation questions were perceived as too difficult and/or time-consuming as compared to questions accompanied with blanks to check or numbers to circle.

In order to obtain more data for the exploratory study, personal interviews were arranged with physicians practicing and/or teaching in the primary investigator's metropolitan area. The approach of personal interviews was opted over a second mailing wave or another mail survey with a different national sample because of financial and time constraints. In addition, it was felt that the response rate of
another mailing would not significantly improve whereas physicians within the investigator's area would likely consent to a personal interview.

After 11 recorded interviews, ranging from 15 to 60 minutes in length, it was determined that little new information would be gathered from additional interviews. Data obtained from these physicians were added to those participating in the mail survey. Responses from the pretest were also included in the final data set since the questionnaire used in the pretest was essentially identical to the one used in the exploratory study. Although the final exploratory study's sample size \(n = 24\) was less than originally desired, it was felt that the quantity and quality of data obtained from the personal interviews offset this limitation.

**Salient beliefs, referents, control factors.** One point that became apparent while conducting the interviews was that physicians found it difficult to answer the questions as presented. For instance, most participants pointed out great differences between their attitudes, behaviors, etc. for minor adverse drug events and serious events. Many felt that minor ADEs occurred frequently, were often not mentioned by patients to their physicians, and were so insignificant in nature that recalling any information about them was nearly impossible. Thus, several physicians provided two different answers during the interview to encompass both types of events. Upon analysis of the pilot data, the investigator decided that the primary research project should restrict its focus to physicians' reporting of serious adverse drug events. Thus, the selection of salient beliefs, referents, and control factors was undertaken in the context of physicians reporting serious adverse events to the FDA.

Analysis of the data provided eight salient beliefs about the consequences of reporting serious ADEs to the FDA, seven salient normative referents, and five
salient factors influencing physicians' control over their SR behavior (see Table 6). Saliency was determined by the frequency in which consequences, referents, and control factors were mentioned by subjects participating in the exploratory study. Most of the salient expectancy-value statements and normative referents are self-explanatory. However, some of the 'control factors' are less clear and deserve elaboration.

'Obligation' was characterized by study participants as a sense of duty fulfillment or altruism. Physicians described 'motivation' or lack of it as motivation in general, inertia, conviction of importance, forgetting to report, and effort required to report to the FDA. Lastly, 'available reporting assistance' included support staff to follow-up flagged ADEs, availability of a pharmacist, drug information resources describing ADEs, an available hot-line number for reporting physicians, and a computerized mechanism for sending an ADE report to the FDA.

The data analysis also provided a large number of belief-evaluation statements characterizing the FDA. For example, many respondents indicated that: (1) they dislike dealing with the FDA because it is a government agency and bureaucratic, (2) the FDA should be less biased than other groups such as manufacturers who assess ADE reports, and (3) the FDA is inefficient and ineffective. These types of statements suggest that physicians' reporting behavior may be influenced not only by their attitude toward the act of reporting (ATT) but also by their attitude toward an object, namely the FDA (ATT).
<table>
<thead>
<tr>
<th>BELIEF-EVALUATION STATEMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Helps the FDA develop a more complete ADE database (BE₁)</td>
</tr>
<tr>
<td>2. Discourages the use of borderline or high-risk drugs (BE₂)</td>
</tr>
<tr>
<td>3. Helps prevent damaging ADEs (BE₃)</td>
</tr>
<tr>
<td>4. Helps fulfill my obligation to practice good medicine (BE₄)</td>
</tr>
<tr>
<td>5. Encourages the FDA to scrutinize the drug (BE₅)</td>
</tr>
<tr>
<td>6. Takes too much time (BE₆)</td>
</tr>
<tr>
<td>7. Involves too much &quot;paperwork&quot; (BE₇)</td>
</tr>
<tr>
<td>8. Poses a legal threat to my practice (BE₈)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NORMATIVE REFERENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. FDA (NR₁)</td>
</tr>
<tr>
<td>2. Hospital Licensing Agencies (NR₂)</td>
</tr>
<tr>
<td>3. Hospital Committees (NR₃)</td>
</tr>
<tr>
<td>4. National and State Medical Organizations (NR₄)</td>
</tr>
<tr>
<td>5. Specialty Practice Organizations (NR₅)</td>
</tr>
<tr>
<td>6. Colleagues (NR₆)</td>
</tr>
<tr>
<td>7. Pharmaceutical Manufacturers &amp; Sales Representatives (NR₇)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONTROL FACTORS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Obligation (Internal, CF₁)</td>
</tr>
<tr>
<td>2. Motivation (Internal, CF₂)</td>
</tr>
<tr>
<td>3. Ability* (Internal, CF₃)</td>
</tr>
<tr>
<td>4. Time (External, CF₄)</td>
</tr>
<tr>
<td>5. Accessible Reporting Forms (External, CF₅)</td>
</tr>
<tr>
<td>6. Available Reporting Assistance (External, CF₆)</td>
</tr>
</tbody>
</table>

* Not identified in pilot study as a salient factor but included in this investigation (see p.162)
Sampling Procedure

Target Population and Sample Selection

The target population relevant to the primary investigation was physicians who provide health care services in the United States. Physicians were defined as any practitioner with a M.D. or D.O. degree. Physicians practicing within the five states where the FDA is currently or has recently conducted pilot studies (Rhode Island, Maryland, Mississippi, Colorado, and Massachusetts) were excluded from the sampling frame. This exclusion was deemed necessary because physicians' awareness of, participation in, and attitudes toward reporting adverse drug events to the FDA are expected to be influenced by the pilot programs.

Subjects for this study were drawn from two target frames: (1) a national frame and (2) a local frame. The national frame was purchased from Buckley Dement, Inc. (Chicago, Ill.) and consisted of 1500 randomly selected physicians practicing within the United States excluding the five states identified previously. However, 187 subjects for the pilot study were first randomly selected from the list and invited to participate in the pilot study. Of the remaining 1313 names, four were not usable, leaving 1309 randomly selected physicians available for the primary investigation's sample. The local target frame included all physicians belonging to the Ohio State University's health plan, a preferred provider organization.

All members of the national random sample and the local sample were invited to participate in the study because the exploratory study suggested that nationally recruited physicians may not readily agree to participate in the investigation. However, including the national sampling frame in the investigation was desirable to provide more generalizable results. The local sample frame was added to increase
both the total number of potential participants and the probability of an adequate number of responders. Since the local sample is affiliated with the University and the investigator had the support of the plan's medical director, it was felt that physicians would more likely agree to participate in the study. However, the inclusion of this sample had implications on the generalizability of the study's results, a concern to be addressed in the final chapter.

Sample Size Determination

One of the primary objectives of this investigation was to examine and compare models depicting physicians' intentions to report serious adverse drug events to the FDA. As previously discussed, the theory selected for basing the proposed SR model, namely the Theory of Planned Behavior, is particularly amenable to statistical analysis with LISREL VII's covariance structural modeling (Joreskog and Sorbom, 1991). Some of the strengths of this type of statistical analysis have been previously described.

The plan to use LISREL in this investigation dictated, in part, the required sample size. A sample size of 200 is recommended as a reasonable number to detect a difference between nested models at an alpha level equal to .05 (Hoelter, 1983). This sample size also helps the LISREL program to converge, resulting in parameter estimates which are valid and stable over repeated analyses. In addition, a sample size of 200 provides a chi-square statistic with sufficient power to test the fit of data to a proposed model (Hayduk, 1987). Improper solutions, such as nonconvergence and negative error variance estimates, become a concern with a sample size less than 100 (Boomsa, 1985). Although sample sizes less than 200 have been used and may provide some valid parameter estimates with the maximum likelihood estimation
(MLE) approach, greater assurance regarding the estimates' validity and stability is gained with the larger-sized sample.

Another study objective was to compare differences in behavioral intentions, attitudes toward the behavior, subjective norms, and perceived behavioral control with respect to physicians' reporting behavior between various classifications of physicians. This type of comparison does not necessitate the use of LISREL because other multivariate techniques are available for testing the differences between multiple independent variables. Although comparisons may be made between two or more unequal sample sizes, the selected multivariate analyses could be adequately conducted with a sample size of 200. On the other hand, if the resultant sample size was large enough to accommodate groupings of physicians (group n approximately = 200), a simultaneous analysis of multiple samples with LISREL could be later used to explain and represent similarities and differences among populations of physicians.

Previous research indicates that physicians who have submitted spontaneous reports to the FDA respond well (response rate = 82%) to a survey administered at a later point in time. However, Rogers' et. al. (1988) study, directed at both previously reporting and nonreporting physicians, encountered a 37% response rate. There were reasons to believe that the response rate in this investigation would be significantly lower than that encountered by Rogers' et. al. First, the questionnaire developed for this study was substantially longer. Second, the low response rate (5.3%) in the pilot study suggested that a low response rate may occur again with the national sample in the primary investigation. However, the data collection instrument developed for the latter investigation was expected to be preferable to the pilot study's instrument. Thus, the initial response rate was anticipated to be much
lower than the 37% achieved by Rogers et. al. but higher than the 5.3% achieved in the pilot study.

An overall response rate of 20% to 25% was anticipated from the sample of recruitable physicians. As previously explained, the response rate for the frame of local physicians was expected to be much higher than the rate for the national frame. To account for returned questionnaires that were incomplete or not usable for other reasons, the percent of physicians agreeing to participate in this study was estimated to be 15% to 20%.

All of the physicians from the randomly selected national frame (n = 1309) were invited to participate in the study. Likewise, all the physicians belonging to the University's preferred provider plan (n = 741) were asked to participate in the investigation. All available physicians in both sampling frames were contacted: (1) to ensure a sample size sufficient for the basic structural equation analysis of nested models with LISREL, (2) to increase the extent to which the data could be statistically analyzed, and (3) to potentially allow a one-year follow-up study with this investigation's participants. Physicians' participation in this investigation was encouraged, yet voluntary.

Data Collection

Development of the Data Collection Instrument

Results of the exploratory study contributed significantly to the development of the final data collection instrument. First, as previously mentioned, physicians provided salient beliefs and referents regarding spontaneously reporting adverse drug
events to the FDA as well as salient factors preventing or facilitating physicians' control over performing this behavior. Second, the exploratory study suggested that physicians would more easily respond to questions pertaining to serious adverse events rather than those of unspecified severity. This narrowing of focus was consistent with the FDA's current emphasis on serious adverse drug events and thus, the development of the measurement instrument included this refinement. Finally, the personal interviews indicated that serious ADEs were not an everyday occurrence in most physicians' practices. Since physicians could not opt to perform the behavior until the event occurred, the final data collection instrument reflected the conditional nature of physicians' reporting by specifying the behavior under question as "... reporting the next serious ADE occurring in [the physician's] practice to the FDA ... ".

The data collection instrument was developed amenable to self-administration via mailing. Several factors supported obtaining information by this route: (1) the overall sampling frame was large (n = 2050), (2) questions relating to the proposed physician's SR model were easily self-administered, and (3) a mail survey design was more economical than personally administered interviews and may have been more easily comprehended by respondents than telephone interviews.

**Item Sequence and Physical Characteristics**

The data collection instrument was composed of five parts (See Appendix B). The first part was the survey's cover page, signed by the primary and the three co-investigators, that explained both the investigation's purpose and how the survey was developed based on physicians' input to the exploratory study. In addition, it
emphasized the importance of physicians' participation in the investigation and assured them that their responses would remain confidential.

The second part was a brief introduction to the study including a description of adverse drug events, physicians' options in reporting them, this investigation's focus on the FDA's reporting system, and the FDA's definition of a serious adverse drug event. The third part contained instructions for use of the scales as recommended by Ajzen and Fishbein (1980, Appendix B).

The last two parts contained the questions developed for subjects' completion. The fourth part included, in the following order, the scales designed to measure: attitude, subjective norm, perceived behavioral control, and behavioral intention. The final section included measures of past behavior as well as demographic characteristics. At the end of the questionnaire, physicians were thanked for completing the survey and asked to provide their name and address if they wanted a copy of the completed project's results.

The final data collection instrument was designed as a booklet. The questionnaire was first copied on both sides of 11" X 17" white paper. The three sheets of paper required to contain the final form of the questionnaire were folded in half and stapled in the middle to create the six-page booklet.

**Pretest**

The data collection instrument was based both on the results of the exploratory study and guidelines provided by other researchers for developing standardized measures of attitude, subjective norm, and behavioral intention (Ajzen and Fishbein, 1980; Ajzen and Madden, 1986; Burnkrant and Page, 1988). Therefore, the reliability and validity of most measures included on the survey instrument were
anticipated to be relatively adequate. Plans for this investigation's assessment of the instrument's reliability and validity are discussed in a later section.

In any case, an evaluation of the developed data collection instrument was undertaken to determine problems in the design of the survey instrument, including: (1) length, (2) format, and (3) wording of the cover letter, instructions, and individual measurement items. A panel of experts, consisting of six faculty members and one physician, was asked to evaluate the instrument. In addition, to obtain a rough estimate of the time required to complete the survey, one health care professional, a pharmacist, was requested to read and respond to the questionnaire as if it were addressed to him.

The results of the panel's evaluation of the data collection instrument led to minor changes in the survey's cover letter, the instructions, and the phrasing of some questions. The one measure of time (16 minutes) for completing the questionnaire suggested that although the survey appeared lengthy, it was easy to read and should not require considerable time to complete. Some panel members voiced their concern about the survey's length due to the anticipated response rate of the investigation's intended participants. However, all items included in the survey instrument were deemed necessary to obtain adequate measures of the constructs in the proposed model of physicians' reporting intentions. Thus, the data collection instrument's length was not changed.

**Questionnaire Administration**

The data was collected by a self-report questionnaire. Each questionnaire was coded with an identifying number so that follow-up was possible. By Tuesday, August 6, 1991, each subject was mailed a packet containing the data collection
instrument and a self-addressed, postage-paid envelope. Subjects were requested to return the completed survey by Friday, August 23, 1991 in the provided envelope.

The packet mailed to the physicians belonging to the University's health plan contained an additional item. The plan's medical director prepared and signed a memo addressed to the physicians which encouraged their participation (see Appendix C). This detail was undertaken in an effort to increase this sample's response rate.

Follow-Up

On Thursday, August 29, 1991, a second wave of packets were mailed to subjects who had not responded to the first mailing. This packet contained the identical questionnaire and another self-addressed, postage-paid envelope. The cover letter for this questionnaire differed slightly from the cover of the first survey but, again, stressed the importance of physicians' participation in the research project (see Appendix D). The packets mailed to the physicians for the University's health plan included a different memo written by the plan's medical director (see Appendix C). As in the first wave, physicians were requested to complete and return the survey in the self-addressed envelope by Wednesday, September 18, 1991.

Definition and Measurement of Variables

This section addresses the definition and measurement of all variables included in this investigation. First, a brief description of the types of variables in covariance structural models with LISREL (Joreskog and Sorbom, 1989) is provided so that the
discussion regarding the variables in the proposed model for physicians' reporting intentions is more comprehensible. Next, the variables in the model proposed in this investigation are defined and the approach taken for their measurement is discussed. Finally, other variables not contained in the model but included in this investigation's data collection instrument are defined and discussed in terms of their measurement.

Types of Variables in Covariance Structural Models

Covariance structural modeling (also referred to as structural equation modeling or analysis of covariance structures) attempts to explain the relationships among a set of observed variables in terms of a smaller set of unobserved variables. The observed variables can be directly measured and are generally referred to as 'measured variables'. Unlike the measured variables, the unobserved variables are hypothesized constructs, or latent variables, which cannot be directly measured. The measured variables are used as approximate indicators of the latent variables; ideally, each latent variable has multiple measurable indicators. For the purposes of this investigation, each construct was measured, when possible, by more than one indicator.

A covariance structural model, then, hypothesizes a specific pattern of relationships among a set of measured and latent variables. The model assumes that the latent variables are generating the pattern or structure among the measured variables. The pattern of relationships among the measured and latent variables is comprised of two parts: a structural model, or component, and a measurement model, or component.
The structural model specifies the relationships among the latent variables. The relationships among the latent variables may be either directional or nondirectional, thus determining whether the latent variable is dependent (endogenous) or independent (exogenous). The error or unexplained variance in using independent latent variables to predict dependent latent variables is called "errors in equations".

The measurement model defines each measured variable as a linear function of a latent variable plus an error term, thus linking the observed variables to the unobserved variables. This error, termed 'errors in variables' is present because the measured variables are not perfect measures of the latent variables.

Although several computer programs exist which perform structural equation modeling, this investigation chose to use Joreskog and Sorbom's PRELIS (1988) and LISREL VII (1989). Table 7 includes some of the terminology used in this investigation's proposed model as prescribed by the LISREL analysis. Issues pertaining to the application and interpretation of the LISREL analyses are addressed in the data analysis section.

The Model of Physicians' Reporting Intentions: Variables

The overall model of physicians' reporting intentions proposed in this investigation consists of several constructs or latent variables which are measured by numerous variables. The latent and measured variables are ones: (1) found in the Theory of Reasoned Action (TRA) model, (2) found in the Theory of Planned Behavior (TPB) model, or (3) developed specifically for this investigation's model.

In general, all questions addressing attitude, belief, evaluation, subjective norm, normative belief, motivation to comply, and behavioral intention (TRA) were phrased and scaled as recommended by Ajzen and Fishbein (1980, Appendix B).
### Table 7
Summary of LISREL Terminology

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>NAME</th>
<th>MODEL FUNCTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\eta$</td>
<td>eta</td>
<td>Dependent Latent Variable (DLV)</td>
</tr>
<tr>
<td>$\xi$</td>
<td>xi</td>
<td>Independent Latent Variable (ILV)</td>
</tr>
<tr>
<td>'x'</td>
<td>---</td>
<td>Measured Variable of ILV</td>
</tr>
<tr>
<td>'y'</td>
<td>---</td>
<td>Measured Variable of DLV</td>
</tr>
<tr>
<td>$\delta$</td>
<td>delta</td>
<td>Error in 'x'</td>
</tr>
<tr>
<td>$\epsilon$</td>
<td>epsilon</td>
<td>Error in 'y'</td>
</tr>
<tr>
<td>$\zeta$</td>
<td>zeta</td>
<td>Error in Equation</td>
</tr>
<tr>
<td>$\gamma$</td>
<td>gamma</td>
<td>ILV------&gt;DLV weight</td>
</tr>
<tr>
<td>$\beta$</td>
<td>beta</td>
<td>DLV------&gt;DLV weight</td>
</tr>
<tr>
<td>$\lambda x$</td>
<td>lambda 'x'</td>
<td>ILV------&gt;'x' weight</td>
</tr>
<tr>
<td>$\lambda y$</td>
<td>lambda 'y'</td>
<td>DLV------&gt;'y' Weight</td>
</tr>
</tbody>
</table>
All of these scales were seven-point and anchored with bipolar adjective pairs such as extremely likely/extremely unlikely or extremely good/extremely bad. For data analyses, the scales were assigned values of +3 to -3 with +3 being extremely likely or good. As previously discussed in Chapter II, there is nothing in either the Theory of Reasoned Action or the Theory of Planned Behavior to suggest that one type of scoring should be chosen over the other. However, the approach toward scoring the scales can be manipulated to change the model's predictive capability and the amount of variance explained in variables. Since the approach taken to conceptualize and measure the constructs in this investigation's proposed model was similar to that of Burnkrant and Page's (1988), all scales were measured in a similar format, i.e. a bipolar fashion.

All questions developed to address the normative determinant of behavioral intention varied slightly from recommendations by Ajzen and Fishbein (1980) and other recent investigators (Ajzen and Madden, 1986; Burnkrant and Page, 1988). Instead of using the phrasing " 'People X' think I should ...... " and "Generally speaking, I want to do what 'People X' think I should do", this investigation substituted " 'People X' would expect me to ...... " and "When it comes to medical issues, I think I should do what 'People X' expect me to do". This phrasing was selected for two reasons. First, it was hypothesized that physicians may feel less threatened in admitting to being influenced by what others "expect" them to do than by what others "think" they should do. That is, it was felt that physicians might strongly believe that they are independent practitioners, never succumbing to what others "think" they should do. On the other hand, they might admit more easily that others had "expectations" and that they might comply with these "expectations". Second, it seemed reasonable to limit the questions to "When it comes to medical
issues" because the behavior under study, i.e. spontaneous reporting of serious adverse drug events to the FDA, was in the context of their medical practice.

The following sections define the variables included in this investigation's model and describe how the measured variables were operationalized to serve as the indicators of the model's latent variables. The dependent latent variables constituting the model's structural component include: Attitude toward the Behavior (ATT), General Subjective Norm (GSN), Perceived Behavioral Control (PBC), and Behavioral Intention (BI). The structural model's independent constructs are: Expectancy-Value (EV) attitude or composite, the Normative Belief-Motivation to Comply (NBMC) composite, the Control Belief-Strength of Influence (CBSI) composite, the Control Belief (CB) composite, Past Behavior (PB), and Attitude toward the FDA (ATTo). Figure 14 illustrates the structural and measurement models of the model proposed in Chapter II as representing physicians' spontaneous reporting intentions.

Attitude toward Behavior

Attitude toward the behavior (ATT) is one of the determinants of behavioral intention. A physician's attitude toward spontaneously reporting the next serious ADE directly to the FDA is the individual's positive or negative evaluation of performing that behavior. This attitude is determined by the salient beliefs about the consequences of reporting to the FDA combined with the evaluation of these consequences.

A direct measure of a physician's attitude toward reporting a serious adverse drug event to the FDA was obtained with four items. The physician was asked to rate the behavior on Good/Bad (ABl), Harmful/Beneficial (AB2), Desirable/Undesirable
Figure 14: Overall Structural and Measurement Models Proposed for Physicians' Reporting Intentions
(A₂), and Worthless/Valuable (A₄) seven-point bipolar scales. Prior research indicating appropriate bipolar adjective pairs to describe physicians' attitudes toward reporting adverse drug events was nonexistent. Therefore, the adjective pairs for this investigation's measures were chosen based on: (1) evaluative factors of the semantic differential scale (Osgood, Suci, and Tennenbaum, 1957), (2) their use in other researchers' attitude measures (Schifter and Ajzen, 1985; Ajzen and Madden, 1986; Burnkrant and Page, 1988), and (3) their perceived appropriateness in describing physicians' attitude toward the behavior under study.

Each of the four Aᵦ items served as a measured variable for the latent variable ATT in the proposed SR model's analysis with LISREL. In other analyses where one attitude measure was required, the four items were averaged to create one direct measure of ATT.

**Expectancy-Value Attitude**

Expectancy-value attitude (EV) is the belief-evaluation composite underlying ATT. In the case of a physician reporting the next serious adverse drug event to the FDA, the composite consists of two elements: (1) the physician's expectancy or belief that reporting the next serious adverse event will lead to 'n' number of consequences, and (2) the physician's evaluation of each of these 'n' consequences. A belief is information gained from direct observation, outside sources, or inference processes that link a given consequence or outcome to the physician's spontaneous reporting behavior. The evaluation of a consequence or outcome is the physician's assessment of the goodness or the badness of the belief outcome.

In this investigation the structural and measurement components of expectancy-value attitude were designated as follows: the latent 'expectancy-value variable' as
EV; the measured 'belief' variable as B; the measured 'evaluation' variable as E; and the measured 'belief-evaluation' products as BE.

The expectancy-value (EV) construct was measured with questions addressing beliefs about spontaneously reporting to the FDA and the corresponding evaluations of the beliefs' outcomes. The physician was asked to indicate the extent to which he believed the eight salient beliefs identified in the pilot study (See Table 6, p.189). These statements were anchored with "extremely likely/extremely unlikely" and included statements such as: (1) "My reporting the next serious ADE occurring in my practice to the FDA would discourage the use of borderline or high-risk drugs" and (2) "My reporting the next serious ADE occurring in my practice to the FDA would pose a legal threat to my practice". For each belief statement, a question to measure the physician's evaluation of the belief's outcome was designed. The corresponding outcome evaluation questions were anchored with "extremely good/extremely bad" and included: (1) "Discouraging the use of borderline or high-risk drugs is ....... " and (2) "Posing a legal threat to my practice is ....... ".

For use in the proposed model's evaluation with LISREL, the measured variables (BE) for the EV composite were generated by performing the appropriate multiplication as is current practice (Ajzen and Madden, 1986; Burnkrant and Page, 1988). The score from each belief question was multiplied by the score from its corresponding outcome evaluation to create eight BE products. Four positive BE products each served as a measured variable of the EV(+) latent variable while four negative BE products were measured variables of the EV(-) construct. Belief-evaluation products were classified as positive (BE1-4) or negative (BE5-8) based on the pilot study's results.
For other data analyses requiring one measure of $EV(+)\text{ and } EV(-)$, the four positive BE products were averaged to produce the $EV(+)\text{ composite score}$. Likewise, to create the $EV(-)\text{ composite score}$, the four negative BE products were averaged.

**General Subjective Norm**

General Subjective Norm (GSN) was used in this investigation to represent the latent subjective norm variable in the proposed model. General subjective norm is one of the determinants of physicians' behavioral intention. It is a physician's perception of the social pressures put on him to report or to not report the next serious adverse drug event occurring in his practice to the FDA.

GSN was operationalized with one measured variable, namely SNMC. This measure consisted of two questions, one addressing subjective norm and the other assessing motivation to comply. The SN question asked the physician to respond to "Most people who are important to me would expect me to report the next serious ADE occurring in my practice to the FDA"; the MC question requested the physician to respond to "When it comes to medical issues, I think I should do what most people who are important to me expect me to do". Both questions were anchored by extremely likely/extremely unlikely. Multiplying the subjective norm question by the motivation to comply question generated the value of GSN for use in the model's analysis with LISREL.

**Normative Belief-Motivation to Comply Composite**

The normative composite underlying subjective norm is commonly referred to as the normative belief-motivation to comply (NBMC) composite. In terms of a
physician's reporting behavior, NBMC consists of two components: (1) the physician's belief that a given normative referent thinks the physician should or should not report the next serious adverse drug event occurring in his practice to the FDA, and (2) the physician's motivation to comply with the given referent.

For the purposes of proposing the structural and measurement components of the overall model depicting physicians' reporting intentions, the following designations were used: the latent 'normative belief-motivation to comply' variable as NBMC; the measured 'normative belief' variable as N; the measured 'motivation to comply' variable as M; the measured 'normative belief-motivation to comply' products as NM.

Seven questions were developed to measure a physician's normative beliefs (N) based on the seven salient normative referents identified in the pilot study (see Table 6, p. 196). An additional seven questions measuring the physician's motivation to comply (M) with each of these referents were also developed. For example, questions addressing one normative belief and its motivation to comply counterpart included: (1) "The FDA would expect me to report the next serious ADE occurring in my practice to them" and (2) "When it comes to medical issues, I think I should do what the FDA expects me to do". All normative belief and motivation to comply scales were seven-point and anchored with extremely likely/extremely unlikely. Again, the score from each N statement was multiplied by the score from its corresponding M measure to create seven NM products serving as measured variables for the latent NBMC variable.

The pilot study suggested that normative referents might belong to one of two categories: an 'authoritative' group or a 'nonauthoritative' group. Those referents assigned to the 'authoritative' (NR_A) group had, to some extent, regulative power
over physicians, physicians' practices, or the hospitals in which physicians had staffing privileges. 'Authoritative' referents identified in the pilot study and specified in the proposed model included: the FDA (NR₁), hospital licensing agencies (NR₂), and hospital committees (NR₃).

The referents assigned to the 'nonauthoritative' (NR₄A) group had no regulative power over physicians or their practices but operated, instead, at a peer, professional, or associate level. The 'nonauthoritative' referents identified in the pilot study and specified in the primary investigation's model included: medical organizations to which physicians belong (NR₄), specialty practice organizations to which physicians belong (NR₅), colleagues (NR₆), and pharmaceutical manufacturers including their sales representatives (NR₇).

For analysis by LISREL of the proposed model, the three NM 'authoritative' products were used as measured variables for the latent NBMCₐ variable; the latent NBMCₐNA variable was measured with the remaining four 'nonauthoritative' NM products. In data analyses requiring one value for the NBMCₐ and NBMCₐNA composites, the three 'authoritative' NM products were averaged to produce one NBMCₐ score and the four 'nonauthoritative' NM products were averaged to generate one NBMCₐNA score.

Behavioral Intention

According to the Theory of Reasoned Action, the immediate antecedent of any behavior of a volitional nature is the intention to perform the given behavior. A behavioral intention (BI) is a "measure of the likelihood that a person will engage in a given behavior" (Ajzen and Fishbein, 1980, p. 42). The Theory of Planned Behavior also specifies BI as a determinant of behavior but recognizes that factors,
internal and/or external to the individual, may also influence the behavior's execution (Ajzen and Madden, 1986). For this investigation, a behavioral intention is defined as the likelihood that a physician will report the next serious adverse drug event occurring in his practice to the FDA.

Behavioral intention was measured with two items. The physician was asked to answer two 7-point scales: (1) "I intend to report the next serious ADE occurring in my practice to the FDA ..... extremely likely/extremely unlikely", and (2) "When the next serious ADE occurs in my practice, I will try to report it to the FDA ...... extremely probable/extremely improbable." The two scales used in this investigation were patterned after two of the BI scales used by Ajzen and Madden (1986), i.e. "I intend to ... " and "I will try to ...". The value from each question served as a measured variable \((I_1, I_2)\) for the 'Behavioral Intention' (BI) latent variable in the proposed model. For the data analyses that required one measure of behavioral intention, the values from the two items were averaged to create one BI score.

**Perceived Behavioral Control**

According to the Theory of Planned Behavior, perceived behavioral control (PBC) is a determinant of behavioral intention and sometimes behavior. PBC refers to the perceived ease or difficulty of performing a given behavior and is assumed to reflect past experience as well as: (1) anticipated impediments or obstacles that may impair or prevent the attainment of the behavioral goal, and (2) anticipated resources and opportunities, i.e. facilities, that may facilitate or improve the behavioral goal's attainment (Schifter and Ajzen, 1985; Ajzen, 1985; Ajzen and Madden, 1986; Ajzen, 1988; Beck and Ajzen, 1991; Ajzen 1991).
As previously discussed, one objective of this investigation was to further the conceptualization and operationalization of the latent PBC variable. A method for assessing the extent to which this objective was met was to compare the measures developed for this investigation to previously developed measures which have received empirical support. As explained in the literature reviewing the Theory of Planned Behavior, the more sophisticated PBC measures published, to date, and therefore the most appropriate for this comparison were the two measures developed by Ajzen and Madden (1986). One of these measures (the direct PBC measure) has been used to some extent by other researchers (Ronis and Kaiser, 1989; DeVellis et. al., 1990; Fishbein and Stasson, 1990; Hinsz and Nelson, 1990; Steffon, 1990; Netemeyer and Burton, 1990; Beale and Manstead, 1991; Beck and Ajzen, 1991; Netemeyer et. al., 1991).

The direct or "global" measure of the PBC construct developed for this investigation attempted to duplicate the direct PBC measure used by Ajzen and Madden (1986). Four questions were designed to globally measure perceived behavioral control. All four items (GC = Global Control) were phrased according to Ajzen and Madden (1986, p. 462, 467): "For me to report the next serious ADE occurring in my practice to the FDA is ...... extremely easy/extremely difficult" (GC₁); "If I wanted to, I could report the next serious ADE occurring in my practice to the FDA ...... extremely likely/extremely unlikely" (GC₂); "It is up to me whether or not I report the next serious ADE occurring in my practice to the FDA ...... extremely true/extremely false" (GC₃); and "When the next serious ADE occurs in my practice, whether or not I report it to the FDA is ...... completely under my control/not at all under my control" (GC₄).
One variation from Ajzen and Madden's (1986) direct PBC measure is the adjective pair anchoring the fourth item. In both experiments conducted by these authors, the scale's endpoints were "complete control" and "very little control". The bipolar adjective pair selected for this investigation's measure was believed to more adequately represent the entire range of perceived behavioral control as conceptualized by Ajzen (1987; 1988). That is, since PBC is characterized as a continuum of perceived control over behavior, ranging from no control at one end of the spectrum to complete control at the other end, it seemed reasonable to reflect this range of possible values on the scale. In addition, anchoring the scale with the bipolar adjective pair offered consistency with the measures of all other variables in the proposed model.

Each of the four GC items served as a measured variable for the latent PBC variable in the proposed model's analysis with LISREL. In analyses requiring one PBC value, the four items were averaged to generate one direct measure of PBC.

Control Belief-Strength of Influence Composite

The remaining items included in the section addressing perceived behavioral control provided two separate measures for testing the hypotheses developed in Chapter II: (1) the Control Belief-Strength of Influence (CBSI) composite, and (2) a measure attempting to resemble the belief-based PBC measure developed and used by Ajzen and Madden (1986, p. 462, pp. 466-467). First, discussion regarding the CBSI composite's definition and operationalization is provided, followed by a brief explanation of the belief-based PBC measure used in this investigation.

In order to specify the measurement and structural models of this investigation, the following designations were made: the latent 'control belief-strength of
influence' composite as CBSI; the latent 'control belief' construct as CB; the measured 'control belief' variable as C; the measured 'strength of influence' variable as S; the measured 'control belief-strength of influence' product as CS.

Control Belief-Strength of Influence (CBSI) is the composite, as developed in Chapter II (p. 149), underlying the latent PBC variable. In the case of physicians' reporting behavior, the composite consists of two elements: (1) the physician's belief or expectancy (i.e. likelihood) that when he encounters the next serious adverse drug event in his {medical} practice, factors 'X' which influence his control over performing the behavior will be available to or possessed by him and (2) the physician's estimate of the strength of influence (SI) these control beliefs have on his actual reporting behavior. In this investigation, factors which influence the physician's control are called 'control factors' (CF), beliefs about the availability or possession of these factors are called 'control beliefs' (CB), and estimates regarding the 'strength of influence' reflect the extent to which the control beliefs facilitate or prevent the physician's reporting behavior, i.e. direction and magnitude.

In terms of operationalizing the control belief (CB) construct, the physician was asked to indicate the likelihood that six 'control factors' would be available to or possessed by him when the next serious adverse drug event occurred in his practice. As discussed in Chapter II, operationalizing beliefs about internal control factors seem semantically more appropriate when worded as "presence" of skills, "have" the skills, "possess' the skills, etc. Therefore, the statements in this investigation, measured on seven-point scales ranging from extremely likely to extremely unlikely, included: "When the next serious ADE occurs in my practice, I will feel obligated to report it to the FDA" (C1); "When the next serious ADE occurs in my practice, I will feel motivated to report it to the FDA" (C2); "When the next serious ADE
occurs in my practice, I will have the ability to report it to the FDA" (C3); "When the next serious ADE occurs in my practice, I will have the time to report it to the FDA" (C4); "When the next serious ADE occurs in my practice, the FDA's reporting form will be accessible to me" (C5); and "When the next serious ADE occurs in my practice, reporting assistance will be available to me" (C6).

All salient 'control factors' that were identified in the exploratory research (see Table 6, p. 196) were incorporated in the items measuring the latent CB variable. Although 'ability' was not identified in the exploratory study as a salient control factor, it was included as a 'control factor' in this investigation for reasons previously outlined in Chapter II (see p. 162). In addition, the potential problem with 'motivation' as a control factor has been previously discussed (see p. 163) and thus, will not be readdressed in this section.

The SI component of the CBSI composite was addressed with six questions corresponding to the three internal and three external control factors selected for study in this investigation. Subjects were asked to respond to six statements, including: "In terms of affecting my actual reporting, feeling obligated to report to the FDA would ....... facilitate/prevent ....... my reporting the ADE." (S1); "In terms of affecting my actual reporting, feeling motivated to report to the FDA would ....... facilitate/prevent ....... my reporting the ADE." (S2); "In terms of affecting my actual reporting, having the ability to report to the FDA would ....... facilitate/prevent ....... my reporting the ADE." (S3); "In terms of affecting my actual reporting, having the time to report to the FDA would ....... facilitate/prevent ....... my reporting the ADE." (S4); "In terms of affecting my actual reporting, an accessible reporting form would ....... facilitate/prevent ....... my reporting the
ADE." (S₅); and "In terms of affecting my actual reporting, available reporting assistance would ...... facilitate/prevent ...... my reporting the ADE." (S₆).

The scales measuring the strength of influence construct were not labeled with the adjectives 'extremely', 'quite', etc. because each item would have been awkward to read. In addition, it was felt that by providing seven equally spaced blanks anchored with bipolar-like verbs, physicians would easily understand the scales. Furthermore, since the scales were fairly consistent with the survey's other scales, it was anticipated that they would provide relatively reliable responses.

Consistent with the derivation of the EV and the NBMC composites, the value from each C item was multiplied by its S counterpart to generate six CS products. Each product served as an indicator for the latent CBSI variable in the model's analysis with LISREL. The two CS products derived from the internal control factors identified in the pilot study, namely 'obligation' (CS₁) and 'motivation' (CS₂) served as measured variables of the internal latent CBSI composite (i.e CBSIᵢ). In addition, the CS product generated from the 'ability' (CBSI₃) factor was the third indicator of CBSIᵢ. Likewise, the three indicators for the external latent CBSI composite (i.e. CBSIₑ) were derived by multiplying the value of the C items with the S items for time (CS₄), accessible reporting forms (CS₅), and available reporting assistance (CS₆).

In other analyses in which one measure for the latent CBSI variable was required, all six CS products were averaged. In analyses requiring one measure for both the 'internal' and 'external' latent CBSI variables, the three products derived from the internal factors were averaged to generate the CBSIᵢ variable and the remaining three products derived from the external factors were averaged to provide the CBSIₑ variable.
The belief-based PBC measures developed and used by Ajzen and Madden (1986) have been previously described in Chapter II (see pp. 145 - 147). In short, one of the belief-based measures used a mixture of 'likelihood' and 'frequency' scales. It was previously argued that since Ajzen and Madden's approach toward operationalizing 'control beliefs' was not clear, the use of 'likelihood' scales in this investigation's belief-based PBC measure was a defensible approach. In addition, it was felt that by not mixing 'likelihood' and 'frequency' items in the same measure, the reliability and validity of the measure would provide a stronger test of any difference between the belief-based (CB) and the proposed CBSI composite as the antecedent of perceived behavioral control.

In developing a measure of the latent control belief variable that was similar to the one developed by Ajzen and Madden (1986), then, this investigation used the six 'likelihood' scales designed to measure the latent control belief (CB) component as the indicators, or measured variables of this construct. For analyses requiring one measure of the latent CB variable, the scores from all six items were averaged to generate the CB value. In other analyses where one measure of the latent 'internal' and 'external' CB variables were needed, the scores from were averaged to generate the value and the scores from were averaged to provide the value.

**Past Behavior**

Past behavior is defined in this investigation as a determinant of a physician's intention to spontaneously report a serious adverse drug event to the FDA. The latent variable 'Past Behavior' (PB) was measured with two indicators: the frequency and recency of past reporting behavior. For this investigation, the
frequency (F) of past reporting was measured for three time periods: (1) within the past 6 months, (2) within the past 1 year, and (3) within the past 2 years. Physicians were asked to report how many serious ADEs had occurred in their practice as well as how many serious ADEs they had reported to the FDA for each of the three times periods. The recency (R) measure of 'Past Behavior' asked physicians to respond to two questions: (1) "When did the last serious ADE occur in your practice?" and (2) "When did you last report a serious ADE to the FDA?".

At the time of the data collection instrument's development, it seemed important to measure both the number of adverse events occurring and the number reported by the physician because of the conditional nature of the behavior. That is, if no serious adverse drug events had occurred in the physician's practice, he could not have reported to the FDA. However, if an event had occurred and the physician did not report it, this past behavior would be different from the past behavior in the previous situation. Specifically, the physician may not have performed the behavior because the opportunity did not exist or the physician may not have performed the behavior because he opted not to report. A similar example can be made for the measure of the recency of past behavior.

The measures of past behavior in this investigation were met with two major difficulties. First, the conditional nature of past behavior has not been previously addressed in the literature, in terms of incorporating valid measures in behavioral intention models. As discussed in Chapter II, Bagozzi and Warshaw (1990) were the pioneers of the 'recency' measure in their study of behavioral intention models. Thus, information pertaining to the operationalization of conditional measures of 'frequency' and 'recency' was not found. Second, a relatively high number of physicians participating in the study had either not encountered a serious adverse
drug event in their practice or had encountered one but had not reported it to the FDA. Therefore, it seemed reasonable to believe that further differentiation of past behavior based on whether an adverse event had occurred or had not occurred may not be advantageous without some guidance.

In addition to the difficulties discussed above, this investigation reexamined the behavior of study: physicians' intentions to report a serious adverse drug event to the FDA. Looking strictly at the behavior of interest, a measure of past behavior should address the physician's past performance of the behavior, not the reasons leading to his past behavior. This area requires further research for a clearer understanding of conceptualizing and measuring past behavior.

In addressing the concerns discussed in this section, this investigation included one measure of frequency and one measure of recency. In terms of the frequency measure, the behavior of interest was the number of adverse drug events reported to the FDA. Due to the relatively infrequent occurrence of serious adverse events, the measure used in the model was 'the number reported within the past two years'. The recency measure was also limited in that the measure used in the model was the 'number of months since the last serious adverse event was reported'.

**Definition and Measurement of Other Variables**

The data collection instrument included measures of other variables, primarily demographic or classification variables pertaining to physicians and their practices. These variables included: (1) the proportion of in-patient versus out-patient practice, (2) whether the physician was a provider for a managed health care plan, (3) the approximate size of the largest hospital in which the physician had admitting or staff privileges, (4) the allocation of the physician's time among teaching,
research, patient care, and other activities, (5) gender, (6) the number of years that
the physician was licensed to practice, and (7) the physician's specialty of practice.
Lastly, each questionnaire was dated when it was received in order to measure the
length of time for the subject's response. This information was important to assess
nonresponse bias.

Evaluation of the Questionnaire

The evaluation of the data collection instrument entails an examination of the
instrument's validity and reliability. In terms of the instrument's validity, the
assessment of three types of validity is of interest in this study, namely content
validity, predictive validity, and construct validity (Nunnally, 1978). In turn,
construct validity includes four components: (1) reliability, (2) convergent validity,
(3) discriminant validity, and (4) nomological validity.

Content Validity

Content validity is obtained when a plan and procedure specifies a detailed
outline for constructing the data collection instrument. Satisfying two major
standards contributes to this detailed outline or "blueprint": (1) selecting items
which are sampled from the appropriate domain of content for inclusion on the final
measurement instrument, and (2) using "sensible" methods for constructing the
questionnaire (Nunnally, 1978).

For this investigation, the first standard was addressed by developing the final
data collection instrument based on the exploratory study's results. In terms of
satisfying the second standard, several approaches were undertaken. First, it seemed
"sensible" to construct the measurement instrument based on data obtained in the exploratory study. Second, constructing the investigation's data collection instrument by following the detailed outline provided by Ajzen and Fishbein (1980, Appendix B) and other researchers' guidelines for measurement development contributed to this standard. Finally, faculty members who frequently develop survey instruments designed for administration by mail commented on the final data collection instrument's content during the pretest.

Predictive Validity

Predictive validity refers to the ability of the measurement instrument to predict a criterion. Predictive validity is achieved to the extent that a predictor (e.g., a scale, measurement instrument) correlate with, or predict, the criterion variable. In terms of this investigation, one criterion was physicians' intention to report the next serious adverse drug event to the FDA. Other indications of predictive validity include: (1) the extent to which attitude, subjective norm, perceived behavioral control, past behavior, and attitude toward the FDA predicted physicians' intentions; (2) the extent to which EV attitude, NBMC composite, PBC composite, and frequency/recency predicted ATTB, GSN, PBC, and past behavior, respectively.

Construct Validity

Construct validity refers to the "the vertical correspondence between a construct which is at an unobservable, conceptual level and a purported measure of it which is at an operational level" (Peter, 1984, p. 134). A more simple and realistic definition is the ability of the items selected for inclusion in the measurement scales to validly measure the constructs they purportedly represent. Ideally, construct
validity exists when a measure assesses the magnitude and direction of all and only all the characteristics of the construct. To the extent that: (1) the construct measures the magnitude and direction of a representative sample of the construct's characteristics, and (2) the construct's measures are not contaminated with characteristics from other constructs' domain, a given construct's validity is ensured. The four components of construct validity, including reliability, convergent validity, discriminant validity, and nomological validity are first briefly described in this section. Next, this investigation's approach toward assessing them is addressed.

Reliability

Reliability is a necessary but not sufficient condition for a measure's validity. Reliability is defined as the "degree to which measures are free from error and therefore yield consistent results" (Peter, 1979, p. 6). Determining measures' reliability is paramount because the magnitude of correlations between different measures depends on each measure's reliability. An unreliable measure attenuates, or lessens, the correlation between two measures or constructs.

The reliability of a measurement scale can be assessed three ways: (1) test-retest, (2) internal consistency, (3) alternative forms. The test-retest method involves applying an identical set of measures to the same subjects at two different times. To the extent that the scores obtained from these times correlate, the set of measures are reliable. The internal consistency method involves correlating a part (i.e. a subset of items) of a multi-item scale with another part of the same scale. Lastly, alternative form reliability correlates scores from two alternative forms of the instrument, administered to the same subjects, at two different times. Again, the higher the correlation, the greater the reliability of the data collection instrument.
Convergent and Discriminant Validity

Convergent validity refers to the correlation between different measures which are measuring the same construct. On the other hand, discriminant validity refers to the lack of correlation between measures which are measuring different constructs. The multitrait-multimethod (MTMM) matrix developed by Campbell and Fiske (1967) is one procedure developed specifically to assess a measurement instrument's convergent validity and discriminant validity; however, it involves several problems (Peter, 1981). Another approach providing substantial information and distinctly advantageous is confirmatory factor analysis or LISREL (1989).

Nomological Validity

Nomological (or lawlike) validity "entails investigating both the theoretical relationships between different constructs and the empirical relationship between measures of those different constructs" (Peter, 1981, p. 135). That is, in addition to the validity of the individual constructs embedded in a theory, nomological validity infers that the relationship among constructs and their measures can be derived from theory. Support for a theory's nomological validity is provided through empirical research.

Evaluating the Instrument's Construct Validity

In evaluating the construct validity of this investigation's measurement instrument, a major concern was to follow an approach which allowed a rigorous evaluation of the constructs' dimensionality. Since three of the independent latent variables in the model were proposed to be multidimensional in nature, evaluating the construct validity of these variables' measures was paramount to comparing
alternative models. An analytical approach that is particularly advantageous in evaluating construct validity is structural equation modeling, a confirmatory factor approach. The advantage of this approach specific to this investigation are discussed after briefly addressing other steps taken in this study to contribute to the instrument's construct validity.

The construct validity of this investigation's data collection instrument is augmented in several ways. First, the existence of content and predictive validity contributes to construct validity. Second, as previously discussed, other researchers have documented the convergent, discriminant, and predictive validity of the Theory of Reasoned Action model. In addition, the TRA's constructs have been evaluated in terms of dimensionality (Burnkrant and Page, 1988). Third, a recent study using LISREL VI's covariance structural modeling provides a basis for assessing the predictive validity and construct validity for the Theory of Planned Behavior (Netemeyer et. al., 1991). Finally, phrasing and scaling the measurement scales as recommended by Ajzen (1980) help support the construct validity of many of the questionnaire's segments.

In terms of assessing the reliability of this investigation's data collection instrument, the internal consistency approach was preferred to the test-retest and alternative forms approaches. The data was analyzed with LISREL VII (1989), because covariance structural modeling allows the calculation of a reliability coefficient, unlike the computation of coefficient alpha, without assuming: (1) the items form a unidimensional set, and (2) the items have equal reliabilities (Gerbing and Anderson, 1988). The results of the LISREL analysis provided the information needed to calculate reliabilities of the model's constructs and the amount of variance extracted by each construct. These indicators of construct validity were used as
recommended by Fornell and Larcker (1981, p.45-46). The 'composite reliability' and 'variance extracted' values were calculated by using Equations 3.1 and 3.2, respectively.

\[
\text{Composite Reliability} = \frac{\left( \sum_{i=1}^{p} \lambda_{yi} \right)^2}{\left( \sum_{i=1}^{p} \lambda_{yi} \right)^2 + \sum_{i=1}^{p} \text{Var}(e_i)}
\]

(Eq. 3.1)

\[
\text{Variance Extracted} = \frac{\sum_{i=1}^{p} \lambda_{yi}^2}{\sum_{i=1}^{p} \lambda_{yi}^2 + \sum_{i=1}^{p} \text{Var}(e_i)}
\]

(Eq. 3.2)

An evaluation of the measurement instrument's convergent and discriminant validity was also obtained with the confirmatory analysis approach (LISREL VII, 1989). This approach is capable of assessing constructs' correlation while correcting for attenuation due to measurement error. Specifically, a structural equation analysis provides an advantage in assessing the internal consistency (or reliability) and external consistency of a multiple-indicator measurement model such as the
overall model proposed in this investigation. Lastly, results from testing the hypotheses provided evidence regarding the proposed model's nomological validity.

Sources of Error and Bias

Not unlike the majority of conducted survey research, this investigation was vulnerable to error and bias. Accordingly, it is prudent at this time to discuss potential sources of error and bias before reporting the study's results. Four categories of potential error sources, corresponding to the basic components of the survey, in this investigation include: (1) errors associated with the frame, (2) sampling errors, (3) errors due to nonresponse, and (4) measurement errors (Lessler, 1984). Lastly, other sources of error such as those introduced by the investigator are discussed.

Frame Errors

A frame error results from an error in defining the target population or in developing a means for identifying and accessing the population's members. For example, a frame error may result from a deliberate decision to restrict the target population to a readily available frame because the time and resources required to identify and/or access the complete frame is not available or practical.

In terms of this investigation, the target population was defined as physicians (either M.D. or D.O.) who provide health care in the United States, excluding the five states in which pilot FDA projects were being or had been conducted. Definition of the target population for this study was intended to tap the group of health care providers who submit the majority of ADE reports to the FDA. Two
separate frames were identified to gain access to this population's members: (1) a national frame, and (2) a local frame.

This study's results may be limited by the extent to which the frames selected for this investigation do not coincide with the intended frame. For example, framing error may be present if this investigation: (1) used inappropriate inclusion criteria (M.D. or D.O.) in defining a physician, (2) made an inappropriate decision in excluding the five states from the national target population, (3) inappropriately restricted the local frame, or (4) used invalid national and/or local target frames, in terms of inaccurate, incomplete, or out-of-date names and addresses.

The first three examples of potential framing error are difficult to assess for this investigation. However, the last example was assessed to some extent. One method used to validate the target frames available for this research involved examining the number of mailed surveys which were never received by the physician because (1) the physician was no longer in practice, (2) the address was incomplete or incorrect, or (3) the nature of the physician's practice excluded them from the intended target population (either they did not prescribe drugs or for some other reason their practice did not involve submitting ADE reports to the FDA).

In this investigation, an error in the target frame appears to pose a higher threat to the national target frame than the local frame. Out of 1309 surveys mailed to the national frame, 15 (1.1%) were returned because the physician was no longer in practice, 84 (6.4%) were returned due to incorrect or incomplete addresses, and 7 (0.5%) were returned due to the nature of the physician's practice. In terms of the local target population (n = 741), the number of surveys returned because (1) the physician was no longer in practice, (2) the address was incomplete or inaccurate, and (3) the nature of the physician's practice was not applicable was 4 (0.5%), 12
(1.6%), and 6 (0.7%), respectively. Therefore, the list representing a randomly selected group of national physicians was only 91.9% (net n = 1203) usable whereas the list representing a local frame of physicians was 97.0% (net n = 719) usable.

**Sampling Errors**

Sampling errors result from a misspecification of the sample design or from inappropriately selecting the sample. For instance, a sampling error occurs when a deliberate decision is made to restrict survey administration to only a sample of the target population.

This investigation's use of two target frames introduced potential sampling errors. The national target frame was a randomly selected list of physicians (as defined in the target population) purchased from an independent agent. To the extent that the list of randomly selected physicians did not adequately represent the national target of practicing physicians, sampling error exists. The nature of the local list of physicians included a census of physicians, as defined in the target frame, who belonged to the University's preferred provider plan.

One method to help assess the extent of sampling error in the national sample was undertaken by comparing demographic characteristics of the randomly selected to nationally published data. This comparison showed to what extent the randomly selected group of physicians represented physicians nationally. One demographic comparison was the proportion of office-based and hospital-based practitioners. The proportion of office- and hospital-based physicians in nationally published data was 70% and 30%, respectively. In this study, physicians were classified into 'office-based', 'hospital-based', or undetermined according to the proportion of their practice that was in-patient versus out-patient. Physicians reporting that more than
55% of their practice was in-patient were classified as hospital-based; those reporting that more than 55% of their practice was out-patient were classified as office-based; and those not falling into one of these categories were classified as undetermined. Results indicated that more than 22% and 65% of the physicians in this study's sample were hospital-based and office-based, respectively whereas 13% could not be classified.

**Nonresponse Errors**

Errors due to nonresponse (i.e. nonresponse bias) result from the inability to solicit a response from each member of a sample. Nonresponse error and methods to address it in survey research has been a concern in the literature (Armstrong and Overton, 1977; Lessler, 1984; Taube, 1987). It is also a concern in this investigation due to the overall low response rate (24.7%) encountered in the mail survey. An appropriate method for evaluating whether nonresponse bias occurred in this investigation is to resample those subjects not responding and determine whether the nonresponders are different from the respondents. However, this approach is infrequently taken because of time and financial constraints as well as large amount of information requested from the data collection instrument.

Several other methods have been suggested for estimating nonresponse bias (Armstrong and Overton, 1977). One involves comparing the results from a survey with "known" values for the population (e.g. age, income). However, the potential problem with this method is that because these "known" values have been derived from another measurement instrument, they, themselves, may not be free of nonresponse bias or other sources of bias. Another method, an extrapolation
technique, is based on the assumption that subjects who respond less readily are more like nonrespondents than those who respond earlier or with less prodding.

This investigation used the "extrapolation" method in assessing nonresponse bias. The first 22% of respondents were compared with the last 10% because the frequency distribution of responding subjects was relatively skewed. Comparisons of attitudes, intention, beliefs were conducted and nine t-tests were performed. Using a family-wise error of .05 (Keppel, 1982), results indicated that no significant differences existed between the two groups. Comparing the first 22% of respondents with the last 18% provided identical results.

Measurement Errors

Measurement error can be caused by many factors including characteristics of the: (1) survey instrument, (2) subject, and (3) investigator and data processing.

Survey Instrument Factors

The design or content of the data collection instrument can be a cause of measurement error. Examples of measurement error associated with this category include: (1) confusing or unnecessary instructions, (2) poorly worded questions, and (3) lengthy or tedious survey, etc.

The data collection instrument developed for this investigation was based on a pilot study, incorporated a standardized format suggested by researchers in this field, and pretested to screen for flaws in its design or content. However, comments obtained from completed questionnaires suggested that some respondents felt: (1) the questions were insulting or ridiculous, (2) the questions were repetitive, and (3)
the survey was lengthy and tedious. This review was not surprising due to the survey's standardized format and the nature of the target population.

Another possible source of error introduced by the design and content of the measurement instrument is subjects' fatigue and boredom in responding to the items. An approach which allows the investigator to assess this potential bias is rotation of the questionnaire's sections. This investigation, however, did not follow this approach and thus, error due to the survey instrument is likely.

Subject Factors

Factors pertaining to the subjects may also be a source of measurement error. Two examples of this type of error relevant to this investigation are subject consistency and social desirability. Subject consistency is a concern because several factors can influence how the subject responds to the questionnaire's items, including the subject's mood, motivation, and attitude, as well as environmental or situational factors. The impact of error caused by inconsistent subjects is difficult to assess because the only way to measure the degree of consistency is to administer the questionnaire at least two times. The test-retest approach was not undertaken in this investigation.

Social desirability is a concern in this investigation due to the nature of the studied behavior. Reporting adverse drug events to the FDA is a beneficial behavior for patients and society as a whole. Therefore, physicians may have felt more compelled to respond in a socially desirable way or to not answer as truthfully. This investigation did not include any measures of social desirability and thus, any impact it had on subjects' responses is unknown. It is hoped, however, that this bias was
minimized by: (1) administering the survey instrument via mail rather than an interviewer, and (2) using a number to identify the questionnaire rather than a name.

Lastly, subject error may have been introduced in this study's results if respondents were unable to provide the information requested of them. This may have occurred if their attitudes, beliefs, etc. regarding spontaneously reporting were not developed due to their lack of knowledge about adverse drug events, reporting mechanisms, or the FDA's reporting system. Any impact on the study's results caused by this bias is also difficult to assess and was not further examined in this investigation. Again, it was hoped that most physicians would have some knowledge about the majority of the questionnaire's content and the survey's brief introduction would fill any gaps without influencing physicians' attitudes, beliefs, etc.

Investigator and Data Processing Factors

Measurement error may have been caused by the investigator and her assistant in processing the completed surveys. This type of error may have occurred during the questionnaire's coding. Protection against this type of error was anticipated by: (1) using a detailed code book, (2) employing one individual to code the data to increase processing consistency, and (3) using one individual to enter the data in a further effort to increase the consistency of processing.

Lastly, if the investigator has expectations or biases about the study's outcome, error may occur during the interpretation of the study's results. Again, determining whether this bias was introduced by the investigator is difficult to assess. Several measures were taken to protect against this error, including: (1) the development of
the proposed model based on past theoretical support, and (2) the development of specific hypotheses to test the model before the data was analyzed.

Data Analysis

This section discusses the data analysis for the primary investigation in two parts. The first part addresses the subjects' response to the questionnaire. The second part describes the analytical techniques used to examine the research questions and test the hypotheses proposed in Chapter II.

Questionnaire Response

Questionnaires included in this investigation's data analysis were received between August 14, 1991 and the cut-off date, October 5, 1991. By the cut-off date, 198 questionnaires were returned by physicians belonging to the national group. Twelve questionnaires were subtracted from this number because: (1) six were returned with brief comments about their desire not to participate in the study, (2) five were returned with no comments, and (3) one was returned by a medical resident who believed that the study was not for residents. Therefore, the national sample yielded 186 (response rate of 15.5%) completed questionnaires.

Of the questionnaires received by the local group of physicians, 288 questionnaires were returned of which 284 were usable. The four questionnaires not usable included three which were less than 20% complete and one which was entirely incomplete with a brief comment regarding the survey's length. The local sample, then, provided a 39.5% response rate.
Four additional completed questionnaires were returned but the numbers identifying the questionnaires were removed and thus, each survey's source was unable to be determined. The final number of completed and returned questionnaires was 474, translating into an overall response rate of 24.7%.

**Analytical Techniques for Research Hypotheses**

Statistical techniques used in this data analysis addressed the research questions and hypotheses developed in Chapter II. Specifically, the analytical techniques answered questions regarding the measurement and structural components of the overall model of physicians' spontaneous reporting intentions proposed in this investigation. Since the measurement and structural components of this model is being evaluated with structural equation modeling (LISREL VII, 1989), a brief discussion of application and interpretation techniques as they apply specifically to the data analysis approach selected for this investigation. This discussion permits a more clear-cut explanation of the specific statistical tests applied to this study's research questions and their accompanying hypotheses. Furthermore, it simplifies and enhances the presentation and interpretation of the study results in Chapter IV.

**LISREL: Application and Interpretation**

The advantages of using LISREL VII (1989), or any other computer program for analysis of covariance structure models, have been addressed throughout this dissertation. The following sections discuss issues regarding the application of the LISREL VII program and the interpretation of its results, as it pertained to this investigation's analysis of the research hypotheses.
Selection of Parameter Estimation Method. As previously mentioned, in the application of LISREL, the researcher assumes that the parameters included in the structural and measurement components have some sort of systematic structure. Ideally, the population’s covariance matrix (i.e. a matrix of the covariances among the observed, or measured, variables in the population) is known and the proposed LISREL model holds exactly in the population. In this case, one could estimate the model’s parameters exactly. However, in practice, the population’s covariance matrix is unknown and the study sample’s covariance matrix must suffice. In this case, the investigator must choose a method for estimating the model’s parameters such that the model’s estimate of the population covariance matrix (\( \Sigma \)) matches the sample’s covariance matrix (S) as close as possible.

The choice of an appropriate procedure for estimating the parameters in this investigation’s proposed model involved several considerations: (1) the estimation procedure’s capability to inferentially test models, (2) prior experience with the estimation technique, (3) previous research supporting the interpretation of the estimation method’s results, (4) the procedure’s need for assuming a multivariate normal distribution, and (5) the procedure’s required sample size.

Although several parameter estimation methods exist, 'Maximum Likelihood Estimation' (MLE) has been the most popular technique (Hayduk, 1988; Anderson and Gerbing, 1988) for several reasons. First, the MLE procedure provides an asymptotically-distributed chi square as an overall goodness-of-fit measure, thus allowing models to be inferentially tested. Other estimation methods such as two-stage least squares (TSLS), instrumental variable (IV) do not provide an inferential measure of model fit; and until the latest version of LISREL, unweighted least squares (ULS) method did not (Hayduk, 1987; Joreskog and Sorbom, 1989).
Second, under the assumption of a multivariate normal distribution of the observed or measured variables, MLE provides the desirable asymptotic estimators which are efficient, consistent, and unbiased. Furthermore, these estimators allow significance testing of the individual parameters since their asymptotic standard errors are available (Anderson and Gerbing, 1988). Generalized least squares (GLS) also provides an inferential measure of fit, but has been less widely applied than the MLE technique.

In terms of prior experience with the estimation technique and previous research supporting the interpretation of the technique's results, a large amount of study has been directed at the MLE method and the performance of fit measures associated with it (Tucker and Lewis, 1973; Bentler and Bonett, 1980; Hoelter, 1983; Boomsma, 1985; MacCallum, 1986; Anderson and Gerbing, 1988; Gerbing and Anderson, 1988; Marsh et. al., 1988; Browne and Cudeck, 1989; Mulaik et. al., 1989). Other estimation methods, such as GLS, are growing in popularity and gaining firm supporters. However, information pertaining to the application and interpretation of this estimation procedure is less available since it has received less attention, to date, in the research community. Therefore, the selection of the MLE approach for analyzing this investigation's results was further supported.

Although the MLE strategy has been the most widely applied estimation technique, violation of the multivariate normal distribution may present some problems. Parameter estimates obtained from at least moderately sized samples appear relatively robust to moderate violation of the multivariate normality assumption, particularly if the distribution is unimodal and symmetric. The overall chi-square statistic and the asymptotic standard errors, however, are more vulnerable to violations of this assumption (Anderson and Gerbing, 1988). The MLE
technique, then, may lead to invalid statistics and parameter estimates if the assumption of a multivariate normal distribution is severely violated. Similar problems with the GLS technique would be expected since its use also requires the multivariate normality assumption.

Asymptotic distribution-free (ADF), available in LISREL VII but not version VI, has been viewed as a major advance in estimating parameters in covariance structure modeling because it allows inferential statistical testing without requiring the rigorous distribution assumption of MLE and GLS. However, its primary disadvantages are that it is a very time consuming procedure, necessitates large sample sizes, and requires large amounts of computer memory, particularly as the number of variables grows larger. In terms of required sample sizes, initial studies suggest that a sample size of 400 to 500 is needed (Tanaka, 1984; Harlow, 1985). It has been suggested, however, that these early reports may actually understate the ADF technique's needs in that sample sizes of 1000 to 1500 may be required. Compared to a sample size of 200 that is recommended for using MLE (Hoelter, 1983; Boomsa, 1985; Hayduk, 1987), the ADF estimation procedure was not considered as the most practical or optimal choice, in terms of ensuring valid results, for this investigation.

The above discussion, then, suggests that the maximum likelihood estimation method was most likely preferable to test the hypotheses included in this investigation's data analysis. The MLE method is further supported in the ensuing discussion of appropriate inferential and descriptive statistics to assess the models proposed by the research hypotheses. A potential problem with choosing the MLE technique was that a severe violation of the multivariate normality assumption could invalidate the results' statistical measures. The violation of this assumption was
assessed with output provided by PRELIS (1988), a companion program to LISREL VII, which preprocessed the study data.

**Input data: Matrix format and specification.** Input of the data required considering: (1) the types of data to be input, in terms of the scale type of each measured variable, (2) the appropriate moment matrix, (3) setting the metrics of the latent variables, and (4) the use of multiplied data as the measured variables, or indicators. In terms of the first consideration, observations were assumed to come from an interval scale and to have the metric properties of a continuous scale. Support for this assumption was provided from previous research assessing the reliability and validity of the semantic differential-type scales comprising this investigation's data collection instrument.

Selecting the appropriate moment matrix format for data input is also a necessary consideration. Data input as a correlation moment matrix format is advantageous because it allows easier interpretation of the results and comparison of the relative strengths of the paths within a model, between alternative models proposed in a study, and between different studies' results. Furthermore, certain problems cited by Anderson and Gerbing (1988) associated with inputting a correlation matrix are corrected with the PRELIS (1988) program, thus removing any previous limitation with its use. Therefore, this investigation used the correlation matrix format for inputting data to the LISREL program.

Input of this investigation's data also involved selecting a method to set the metric (i.e. establish a scale) for each latent variable in the model. This procedure is a necessary (but not sufficient) condition for identification of the measurement model. For the independent latent variables, the preferred method is to fix the
entries on the diagonal of the phi matrix (variance/covariances of independent latent variables) at 1.0, rather than arbitrarily fix one pattern coefficient for each variable at 1.0 (Gerbing and Hunter, 1982). This method gives all independent variables unit variance and allows the investigator to test the significance of each estimated pattern coefficient estimate. For the dependent latent variables, only one method exists to establish their scale since the LISREL model does not allow these variables to correlate. Thus, the scale for the dependent variables was established by arbitrarily fixing one pattern coefficient in each column of the lambda_y matrix at 1.0.

Finally, multiplied data served as the indicators, or measured variables, of: expectancy-value attitude, the normative belief-motivation to comply composite, the control belief-strength of influence composite, the attitude toward the behavior construct, and the attitude toward the object. This poses a problem that was addressed to some extent in Chapter II (see pp. 119-120). According to Bagozzi (1990), the presence of product terms for beliefs times evaluations, normative beliefs times motivation to comply, etc., makes it inappropriate to perform causal modeling of the central hypotheses. His suggestion and recent approach in comparing multiplicative, nested models is to use hierarchical regression analyses. Others have suggested applying an 'optimal scaling' approach to the scores of belief, evaluation, etc. scales, in an attempt to improve the correlation between the predictor products, such as b_i e_i and the criterion, i.e. ATT (Holbrook, 1977; Ajzen, 1991). Bagozzi (1984) cautions, however, that while 'optimal' scaling may provide the highest possible correlation between the predictor and the criterion, i.e. satisfy predictive validity, there is a problem in knowing whether the coding is valid unless it is based on a priori conceptual criteria.
This investigation elected to use the LISREL approach for data analysis for several reasons. First and foremost, although regression analyses may provide differences in fit between models, the technique does not allow one to assess the dimensional nature of constructs. The constructs of which the dimensionality is of interest are the ones with indicators consisting of multiplied product terms. There appears to be no apparent statistical technique available that could be used to assess the dimensionality of the EV, NBMC, and CBSI composites besides structural equation analysis.

A second reason for preferring the use of LISREL over regression analysis is that the former technique does correct for measurement error in the model's indicators whereas the latter does not address measures' unreliability. This is a major disadvantage in using regression analyses because the path coefficients are likely to be less "true" than those provided from a structural equation analysis.

Although this investigation recognized the problems posed with the use of structural equation analysis in multiplicative models, it seemed reasonable that its advantages outweighed its disadvantages. In this specific investigation, one major purpose of its use was to compare alternative models within the behavior of study (i.e. physicians' reporting) rather than determining the absolute amount of variance explained in behavioral intention. In addition, since this investigation scored its scales identical to Burnkrant and Page (1988), the comparison of results from some of the research hypotheses could be compared. Furthermore, this study intended to compare its results with the only other published research, to date, that had used confirmatory factor analysis in testing the Theory of Planned Behavior.

Although Netemeyer et. al. (1991) did not report the scores they assigned to their 7-point scales, the bipolar adjective anchors they mentioned suggest that their
scales were scored similarly to the scales developed for this investigation. Therefore, although some evidence suggests that some problems may exist in comparing models fitted with data submitted as product terms and analyzed with LISREL, this investigation chose to estimate and compare the overall model of physicians' reporting intentions with those models proposed by other researchers by using LISREL.

Assessment of fit: Inferential and descriptive statistics. The data analyses applied to this investigation's research hypotheses produced both inferential and descriptive statistics. In terms of an inferential measure, the MLE method provides an asymptotically correct chi-square. The power of the chi-square test is reduced with small sample sizes and the likelihood of failing to reject the null hypothesis ($H_0$: the specified model holds exactly in the population) is greatly increased. However, with the size of samples required to provide stable parameter estimates ($n = 200$), the chi-square test tends to reject null hypotheses even if they are only slightly false. Therefore, supplementing this inferential test with descriptive goodness-of-fit measures is prudent for assessing a model's fit to the data.

Several descriptive goodness-of-fit measures have been proposed by previous researchers. These measures can be classified as: (1) stand-alone indexes, (2) Type 1 incremental indexes, and (3) Type 2 incremental indexes. These classes are first briefly discussed followed by a description of some of the indexes included in the classes (Marsh et. al., 1988).

Stand-alone indexes are based on the results of just one model, e.g. the target model, the model of interest in the study. Many of these measures are provided in the LISREL output or can be easily calculated from it. Examples of stand-alone
indexes that are discussed later include: LISREL's root-mean-square residual (RMR), goodness-of-fit index (GFI), and adjusted goodness-of-fit index (AGFI).

Type 1 and Type 2 indexes are both based on the differences between the target model and an alternative model. However, they measure slightly different aspects of a model's goodness-of-fit. A Type 1 goodness-of-fit index is one which reflects the improvement in fit offered by a model over a baseline or more restricted model, such as the null model. As noted by Mulaik et. al., (1989, p. 434) "the Type 1 index . . . indicates the proportion of the information about associations between variables explained by a model . . . for small samples less than 200 in size, (they) significantly underestimate the asymptotic value of the same index". Examples of Type I indexes that are used in this investigation include the Tucker-Lewis Index (TLI) and the parsimonious goodness-of-fit index [PGFI(1)].

The Type 2 class of indexes address the fit of a model as compared to the 'true' model. This class of indexes tend to underestimate their asymptotic value to a lesser extent in sample sizes less than 200. According to Mulaik et. al. the choice between a Type 1 and Type 2 index is irrelevant in large samples because the Type 2 index asymptotically equals the asymptotic value of the Type 1 index. The use of Type 2 indices is advantageous, in any case, because it is a less biased estimator in sample sizes that are smaller than required to provide a asymptotic value of a Type 1 index. Examples of Type 2 indexes that are used in this investigation are the parsimonious normed-fit index [PNFI(2)] and the relative normed-fit index [RNFI(2)].

As previously mentioned, LISREL VII (1989) provides three stand-alone goodness-of-fit indexes, including GFI, AGFI, and RMR. The GFI is a ratio measure which is not explicitly a function of sample size but its distribution does depend on it. The AGFI adjusts for the model's degrees of freedom but has been
shown to have serious shortcomings (Marsh et. al., 1988). Joreskog and Sorbom (1989) suggest that both GFI and AGFI should be between zero and one. However, information discriminating good or adequate values from bad or inadequate values is lacking in the literature. In addition, these measures can behave irrationally by not providing consistently interpretable values, are affected by violations of MLE assumptions, and can even take on negative values (Marsh et. al., 1988; Mulaik et. al., 1989). In a recent analysis of the effect of sample size on these indices, Marsh et. al. (1988) reported that both of them were substantially affected by sample size. Mulaik et. al. (1989) reject the AGFI (MLE) measure; however, they recommend using GFI (MLE) when the assumption of multivariate normality is satisfied and the sample size is at least 200.

The root mean square residual (RMR) evaluates the overall fit of a proposed model by measuring, on the average, how closely the model is fitting each entry in the sample's covariance matrix. When the data is input as a correlation matrix, RMR is strictly bounded by 0 and 1, thus providing an interpretable means for assessing a model's fit to the data. According to Marsh et. al.'s (1988) analysis, however, the RMR measure provided by LISREL was also substantially affected by sample size.

In addition to providing a RMR measure for an overall model, LISREL VII (1989) computes "fitted residuals" (or fitted moments) from fitting the model to the data's covariance or correlation matrix. Inputting the sample's correlation matrix generates "standardized residuals" (known as normalized residuals" in LISREL VI) which can be roughly interpreted as $Z_{\text{critical}}$ values. These values indicate precisely where the model may poorly fit the sample's covariance matrix and in Anderson and
Gerbing's experience (1988), are the most useful source for identifying the source of misspecification in a multi-indicator model.

LISREL VII, not unlike the previous LISREL versions, provides other detailed information pertaining to the proposed model's structural and measurement components which are useful for analyzing the fit of models proposed in this investigation to the sample data. The program computes a 't-statistic' (a ratio of an estimated parameter to its standard error) which can identify a nonsignificant parameter (less than or equal to 1.96). In addition, modification indices (MI) indicate the minimum decrease in chi-square if a fixed or constrained parameter were relaxed and the model was reestimated. Lastly, LISREL provides measures of explained variance (or variance accounted for), including: (1) squared multiple correlations (SMC) for each observed variable separately and each structural equation, and (2) coefficients of determination for all the observed variables jointly and all structural equations jointly. All of these indices may be useful during a specification search because they identify potentially misspecified model parameters.

The above discussion suggests that several indices provided by LISREL VII were appropriate for evaluating how well the models proposed in the research hypotheses fit the sample data. These included the chi-square as an inferential test of fit, and descriptive measures including: (1) standardized residuals, (2) modification indices, (3) t-statistics, and (4) measures indicating explained variance. It was expected that the chi-square would be significant since the sample size was relatively large (474) and thus, more detailed information regarding the model's fit would be necessary. The sample size's adequacy was also expected to decrease the likelihood of inadequate parameter and standard error estimates as previously described. Although limitations with LISREL's goodness-of-fit index (GFI) and adjusted
goodness-of-fit index (AGFI) were recognized, the GFI measure was included for assessing models in order to compare this investigation's results with other studies (Burnkrant and Page, 1988; Netemeyer et. al., 1991). However, other measures of overall goodness-of-fit were considered for evaluating the models' fit to the sample data.

Recent literature has defined and evaluated several overall goodness-of-fit indices other than those provided in a LISREL analysis (Hoelter, 1983; Marsh et. al., 1988; Mulaik et. al., 1989). Four such measures were selected in this investigation's data analysis to evaluate the fit of the proposed models to the sample data: (1) Tucker-Lewis Index (TLI), (2) parsimonious goodness-of-fit index, Type 1 [PGFI(1)], (3) parsimonious normed-fit index, Type 2 [PNFI(2)], and (4) relative normed-fit index, Type 2 [RNFI(2)].

The Tucker-Lewis Index (TLI), was originally proposed by Bentler and Bonett (1980) and referred to as 'rho' or 'nonnormed fit index'. Bentler an Bonett's 'rho' index is a generalization of the Tucker Lewis coefficient (1973), an index for assessing factor models of an exploratory nature. This index (hereafter referred to as the Tucker Lewis Index) is a ratio of the improvement of fit when proceeding from a null model to a proposed model (numerator) to the improvement of fit when going from a null model to a hypothetically perfect model (denominator). Therefore, this index is classified as a Type 1 index. The index, as defined by Marsh et. al. (1988, p. 393), is provided in Equation 3.3:
\[
TLI = \left( \frac{X_n^2/df_n - X_t^2/df_t}{X_n^2/df_n - 1.0} \right)
\]

Eq. 3.3

where \( X \) is the 'chi-square', \( n \) is the 'null' model, and \( t \) is the 'target' or model of 'interest'. The value of the index ranges from 0 to 1; a value greater than .90 is an indication of good fit of the model to the data but an index around .95 is preferable. Although this index has received some criticism as an overall goodness-of-fit measure (Hoelter, 1983; Hayduk, 1989), Marsh et. al. (1988) favor this index because it is relatively independent of sample size. Netemeyer et. al. (1991) have also applied this index in their confirmatory analysis of The Theory of Reasoned Action and the Theory of Planned Behavior.

The other three fit measures selected for this investigation's data analysis were developed by Mulaik and his colleagues (1989) and include: PGFI(1), PNFI(2), and RNFI(2). According to Mulaik et. al. (1989) and demonstrated in a Monte Carlo simulation, the major drawback of the traditional descriptive goodness-of-fit indices (e.g. Bentler and Bonett's indices, Joreskog and Sorbom's GFI) is that their values can approach unity by simply freeing up more parameters in the model. Unfortunately, this process often leads to inflated measures of fit and a less parsimonious model. In addition, if the measurement model is well-specified, inflated measures may also be obtained even when the structural model is seriously misspecified or invalid. Measures such as PGFI(1), PNFI(2), and RNFI(2) address the issue of parsimony by adjusting fit or lack-of-fit indexes, thus providing indexes useful for evaluating and/or comparing models.
The PGFI(1) index is calculated by adjusting LISREL’s GFI. This index, as defined by Mulaik et. al. (1989) is provided in Equation 3.4:

\[
PGFI(1) = \frac{2d}{k(k + 1)}GFI
\]

Eq. 3.4

where \(d\) is the degrees of freedom of the tested model, \(k\) is the number of observed variables in the model, and GFI is the goodness-of-fit index provided by LISREL. According to Mulaik et. al. (1989, p. 440), the PGFI(1) is used "when the aim is to account for all of the information in the variance-covariance matrix for the observed variables.

The PNFI(2) accounts for just the relationships between the observed variables and subsequently only the covariances between the observed variables. This index is also calculated with output provided by LISREL and is represented, as defined by Mulaik et. al. (1989, p. 440), in Equation 3.5:

\[
PNFI(2) = \frac{2d}{k(k - 1)} \left[ \frac{F_0 - F_j}{(F_0 - d)} \right]
\]

Eq. 3.5

where \(d\) are the degrees of freedom of the model being tested, \(k\) are the number of observed variables, \(F_j\) is the lack-of-fit index (e.g. chi-square) for the model being tested, and \(F_0\) is the lack-of-fit for the null model.
The RNFI applies the parsimony principle in such a way to provide a measure for assessing the structural relations among latent variables independent of the measurement model. The definition of RNFI(2), as provided by Mulaik et. al. (1989, p. 443) follows in Equation 3.6:

$$\text{RNFI}(j) = \frac{(F_u - F_j)}{|F_u - F_m - (d_j - d_m)|}$$

Eq. 3.6

where $F_u$ is the lack-of-fit index (e.g. chi-square) for the model of uncorrelated latent variables, $F_j$ is the lack-of-fit index for the model being tested, $F_m$ is the lack-of-fit index for the measurement model, and $d$ is the degrees of freedom.

The Monte Carlo study conducted by Mulaik et. al. (1989) obtained several indexes of fit, including PNFI(1), PNFI(2), GFI, PGFI(1) and RNFI(2), for six estimated models: (1) null model, (2) uncorrelated factors model, (3) misspecified model, (4) correct model, (5) measurement model, and (6) saturated model. Study results indicated that substantial disparity existed among the measures. The authors concluded from their results that the GFI was relatively high for the correct model (.949) as well as the misspecified model (.911). The parsimonious normed fit indexes, PNFI(1) and PNFI(2), provided smaller values of fit for the misspecified model than the correct model; however, the spread between the two models was minimal. For example, the misspecified model obtained a PNFI(1) and PNFI(2) of .806 and .849, respectively whereas the correct model attained values of .852 and
.897. This lack of spread between the indices was also an issue with PGFI. Specifically, the value of the misspecified model was .772 and the correct model's value was .797. The RNFI(2) provided the clearest picture of the difference between the misspecified (.774) and the correct model (.988).

In their confirmatory analysis of the Theory of Planned Behavior, Netemeyer et. al. (1991) included the RNFI (as well as GFI and TLI) as a measure of their models' overall goodness-of-fit. This investigation's selection of RNFI(2), as well as GFI and TLI, then, permits comparison of this study's results to previous research examining the Theory of Planned Behavior with structural equation analysis.

A final concern with model assessment is the use of a specification search for improving the model’s fit or parsimony (i.e. get closer to the "true model"). This investigation's specific approach for identifying and changing misspecification errors is addressed in a following section. Regardless of the approach undertaken, however, the specification search generates a modified model which may have capitalized on chance characteristics of the sample and thus, further efforts to validate the modified model should be taken.

One method for validating a modified model is by calculating a cross-validation index. Cudeck and Browne (1983) support the use of this index as one method, used in conjunction with other considerations such as theoretical meaningfulness, for comparing the appropriateness of alternative models. The index indicates which models under study are stable under cross-validation. Until recently, cross-validation involved splitting an original sample into two halves and fitting the model to one of the halves. Cudeck and Browne refer to this half as the 'calibration sample'. The second half, referred to as the 'validation sample', is used to calculate
a 'cross-validation' coefficient. One problem in using this approach is that a sample size large enough to provide two halves for individual data analysis is required.

Browne and Cudeck (1989, p. 448) have recently provided guidance for calculating the cross-validation index with a single sample. The advantages of this statistic are that its calculation is based on splitting the sample all possible ways and it is relatively simple to calculate from LISREL's output. In the case of maximum likelihood under the assumption of multivariate normality, this single-sample statistic is simply a rescaled Akaike Information Criterion (AIC), a well-known approach used to select among several alternative models. Thus, this index is also useful in evaluating the appropriateness or stability of alternative models under cross-validation. Browne and Cudeck (1989, p. 451) provide Equation 3.6 for calculating the cross-validation index \( c^* \) for model 'k':

\[
\begin{align*}
    c^*_k &= F_{ML}(S_{c^*}, \Sigma_{kc^*}) + 2q_k/(n-p-1).
\end{align*}
\]

(Eq. 3.7)

where \( F_{ML}(S_{c^*}, \Sigma_{kc^*}) \) is the statistic obtained from minimizing the discrepancy function, i.e. chi-square; \( q \) is the number of parameters in the model to be estimated; \( p \) is the number of measured variables; and \( n \) is the sample size.

In summary, both inferential and descriptive measures were selected to evaluate the models proposed in this investigation's research hypotheses. Specifically, chi-square was chosen as the inferential goodness-of-fit measure. Descriptive measures included: (1) Goodness-of-fit index (GFI) provided by LISREL VII (1989), (2)
Tucker Lewis Index (TLI) as defined by Marsh et. al. (1988, p.393), and (3) Parsimonious normed-fit index [PNFI(2)] and Relative normed-fit index [RNFI(2)] as defined by Mulaik et. al. (1989, pp. 440, 443). Other detailed information provided in LISREL's output were evaluated, including: (1) measures of variance accounted for (e.g. SMC, coefficients of determination), (2) modification indices (MI), (3) T-Statistics, and (4) standardized residuals.

Comparing alternative models: Nested models. The concept of nested models is particularly important in this investigation's data analysis. Models can be hierarchically framed, or nested, in which one model is considered as a specialization or subset of another model. Although Bentler and Bonett (1980) define two types of model nesting (i.e. parameter-nested sequence of models and covariance matrix-nested sequence of models), the concept of a parameter-nested sequence of models seems to be the most popular approach and is the one employed in this investigation.

A parameter-nested sequence of models is a sequence of similar models in which the models have the same parameters but their sequence is ordered according to increasing constraints placed on the free parameters. Simply stated, Model 'A' is nested in Model 'B' if the free parameters of 'A' constitute a subset of the free parameters of 'B'. In terms of this investigation's hypotheses, nested models to be analyzed include: (1) The Theory of Reasoned Action nested within the Theory of Planned Behavior, (2) the unidimensional representation of the EV composite nested within its multidimensional representation, (3) the unidimensional representation of the NBMC composite nested within its multidimensional representation, (4) the
unidimensional representation of the CBSI composite nested within its multidimensional representation, etc.

The major advantage of using nested models in an analysis of covariance structures is that the competing models can be inferentially compared by the chi-square difference test (Bentler and Bonett, 1980; Mulaik et. al., 1989). The chi-square difference test involves determining the difference between two competing models' chi-squares. This difference is also distributed as a chi-square with the degrees of freedom equal to the difference in the two models' degrees of freedom. If the chi-square is significant, then this test implies that: (1) the restriction(s) added (i.e. the gain in parsimony) significantly worsened the model's fit, or (2) the addition of a free parameter(s) (i.e. the loss in parsimony) significantly improved the fit. In this investigation, nested models were evaluated with the previously defined descriptive measures of fit [e.g. GFI, TLI, PGFI(1), and PNFI(2)] to determine if differences between them were significant and/or practical. The RNFI(2) index of fit was not used in these comparisons because while the alternative models shared the same 'null model', they did not share the same 'uncorrelated factors' or 'measurement' models that are needed to calculate RNFI(2).

Comparing alternative models: Nonnested models. Comparing alternative models which are not nested is also an integral part of this investigation's data analysis. Models are not nested if one model's parameters are not a subset of another model, i.e the models are based on different sets of observed or measured variables. The disadvantage of comparing alternative yet nonnested models is that the investigator is unable to inferentially compare the two models with a chi-square
difference test. Nevertheless, competing models can be compared with other overall goodness-of-fit measures.

Generally speaking, when comparing alternative models which are not nested, the model with the smaller chi-square is preferred because it can be assumed that this model's population covariance matrix more closely matches the sample's covariance matrix (Hayduk, 1988). However, its presumed advantage in fitting the data must be balanced with its loss in parsimony. Therefore, in comparing nonnested models in this investigation, the chi-square statistic was supplemented with the selected descriptive measures of overall fit [TLI, PGFI(1) PNFI(2), and RNFI(2)].

**Modeling approaches: Background.** The growing use of structural equation analysis in the social and behavioral sciences is largely due to the advantages it offers researchers. Problems emerge, however, when an appropriate modeling approach is not selected or followed (Anderson and Gerbing, 1988). For example, the technique is fairly sensitive when: (1) latent variables and their indicators are not clearly defined, (2) the structural model lacks theoretical support or is posited haphazardly, or (3) the study is poorly designed.

According to MacCallum (1986), a typical approach to covariance structure modeling is to: (1) develop a model which specifies a pattern of relations among a set of observed (measured) and unobserved (latent) variables, (2) fit the model to sample data, (3) evaluate the solution in terms of overall goodness-of-fit measures and parameter estimates, and (4) modify the model so as to improve its fit to the data or its parsimony. At the point where the model is modified and refit to the
data, a specification search is initiated and the investigator departs from a pure confirmatory approach to an exploratory one.

In MacCallum's (1986) study on the likelihood of success in specification searches, the most frequently successful searches were ones in which: (1) a large sample was used, (2) the number of specification errors was few (i.e. the investigator's initial model was close to the "true" model, (3) a restricted strategy was used in that rigid justification for modifications, in terms of substantial and practical improvements, was established. Lastly, cautions were attached to models arising from specification searches and recommendations for their cross-validation were strongly advised. Another method addressing the cross-validation issue, namely Browne and Cudeck's (1989) single-sample cross-validation index, was previously described.

Recently, two new approaches which offer unique advantages in modeling covariance structures have been described in the literature. Anderson and Gerbing (1988) suggest a two-step modeling technique in which the measurement model is initially estimated and respecified (via specification search) before the final measurement model and a series of nested structural models are simultaneously estimated. This two-step approach purportedly minimizes potential "interpretational confounding" when a model parameter is misspecified. Interpretational confounding is defined as occurring when a latent variable is assigned empirical meaning that is different than the meaning assigned to it in the proposed structural model. Anderson and Gerbing (1988) contend that the potential for interpretational confounding is minimized by prior and separate estimation of the measurement model because no constraints are placed on the structural parameters that relate the estimated constructs to one another. With the use of a one-step modeling approach, however,
interpretational confounding may preside but not be detected, resulting in maximizing the model's structural fit at the expense of meaningful interpretability of the constructs.

The second recently described modeling approach also provides a means for assessing a model's structural component independent of its measurement component. The relative normed-fit index (RNFI), as described in the previous discussion of goodness-of-fit measures, addresses the issue of interpretational confounding and is calculable from this modeling approach. This approach stems from Bentler and Bonett's (1980) nesting concept, is expanded by James et. al. (1982) and Mulaik et. al. (1989), and is applied by Netemeyer et. al. (1991). It involves testing a series of nested models obtained from a single covariance matrix, including: (1) the null model, (2) the uncorrelated factors model, (3) the proposed model(s) of interest, (4) the measurement model, and (5) the "just identified" or "saturated" model. Each model is described below.

First, the null model, originally posited by Bentler and Bonett (1980), specifies no relationships among any of the observable or latent variables, i.e. every pair of variables lacks any covariation. Second, the uncorrelated factors model (James et. al., 1982) is a confirmatory factor model which specifies no relationships among the latent variables but allows for covariation among observed variables. Third, the models of interest covariate as hypothesized by the investigation. Next, the measurement model is a confirmatory factor model for the proposed set of relationships between the measured variables and their corresponding latent constructs (James et. al, 1982). In addition, the measurement model is a structural model in which all one-way pathways among the latent constructs are estimated (i.e. saturated) but the loadings of the measured variables are restricted to their respective
latent constructs and are not allowed to cross-load to other latent variables. Finally, the "saturated" or "just identified" model is one in which the number of parameters to be estimated is equal to the number of independent elements in the observed covariance or correlation matrix (James et. al., 1982).

The modeling approach: Selection for this investigation. In selecting an appropriate modeling approach for this investigation's data analysis, the goals of the research project were re-examined. Specifically, this investigation sought answers regarding both the measurement of the latent variables and the structural relationships among them. To provide such answers, the modeling approaches described in the previous section were evaluated and compared in terms of their ability to meet the needs of this study's goals.

In general, the modeling approach selected for this investigation needed to address the measurement and structural submodels of the latent variables of primary interest, i.e. the behavioral, normative, and perceived control submodels, as well as the overall structural model of physicians' reporting intentions. Although the submodels for ATT and GSN have been addressed in other investigations (Bagozzi, 1981a; Bagozzi, 1981b; Burnkrant and Page, 1988), the need to validate them in this area of study has been previously discussed. Furthermore, the submodel proposed in this investigation for PBC has not been previously examined and hence, it was important to also validate its measurement and structural components.

The above discussion suggests that a two-step modeling approach would be more advantageous than a one-step approach because the former would provide a means to assess the submodels' structural and measurement components before estimating the overall structure of the reporting intention model. However, the two-step approach
recommended by Anderson and Gerbing (1988) was not followed because of its exploratory rather than confirmatory nature. This investigation opted to minimize the risk of capitalizing on the chance characteristics of the study data by proceeding with the generally-accepted 'confirmatory' modeling approach.

The modeling approach of this investigation did entail two steps. However, these steps did not involve the respecification of models or the deletion of any variables from the models; rather, the hypotheses proposed in Chapter II were tested in two stages: (1) the test of hypotheses regarding the submodels and (2) the test of hypotheses regarding the overall model of physicians' reporting intentions. For each component of the overall intention model (i.e. behavioral, normative, and perceived behavioral control), the first stage identified the submodel, from the set of alternative submodels, that best fit the sample data. The selected submodels were then included in the overall model of physicians' reporting intentions for the second stage of modeling.

The second stage of this investigation's modeling approach involved estimating and comparing the series of nested models recommended and defined by James et. al. (1982), and applied by Mulaik et. al. (1989) and Netemeyer et. al. (1991). Specifically, the models examined in the data analysis included the null model, the uncorrelated factors model, the proposed models of interest (i.e. TRA, TPB, etc.), the measurement model, and the just-identified model. The estimation of this series of models allowed the calculation of Type 1 (i.e. TLI) and Type 2 [i.e. PNFI(2), RNFI(2)] goodness of fit indices. In addition, since the RNFI(2) index provides a means to assess a model's structural component, independent of its measurement component, it addresses the issue of 'interpretational confounding' discussed by Anderson and Gerbing (1988).
After completing the second stage of modeling and identifying the overall reporting intention model which best fit the study data, a specification search was initiated to modify the model so as to improve its fit. The model's measurement component was examined for misspecifications first, followed by its structural component. Indicators of misspecifications included high modification indexes (relative to the overall chi-square), standardized residuals, and t-values.

Modifications in the overall reporting model were made one at a time, as recommended by MacCallum (1986). The decision to respecify a parameter was based on the extent to which its respecification would improve the model's fit to the study data as well as the theoretical justification of respecifying the parameter. Upon completion of each modification, the resultant model was evaluated with the goodness-of-fit indices used in the second modeling stage. The use of inferential testing was not an option due to the exploratory nature of the specification search.

The number of modifications were kept to a minimum, balanced with the extent to which further respecification could practically improve the model's fit and be justifiable. Lastly, single-sample cross-validation indexes were calculated for: (1) the model identified, from the pool of alternative models, as best depicting physicians' reporting intentions and (2) the model resulting from each specification search. These indices were used in conjunction with the goodness-of-fit measures for evaluating and comparing the models.

Analysis of Research Questions and Hypotheses

The first four research questions address the measurement and structural components, or 'submodels', of ATT, GSN, and PBC. The results generated from testing the hypotheses developed for these four questions provided the most
appropriate 'submodel' from the submodels proposed (i.e. before respecification of any of the submodels), to include in the overall model of physicians' reporting intentions.

**Research question 1.** The first research question addressed the structure, or underlying dimensional nature, of expectancy-value attitude within the Theory of Planned Behavior. Specifically, the question proposed that expectancy-value attitude is better represented as a two-dimensional rather than a unidimensional structure. This proposition is tested in Hypothesis 1.1.

**H1.1:** A two-dimensional model of expectancy-value attitude in which one dimension represents the positive and the other represents the negative consequences of reporting a serious ADE to the FDA will provide a significant improvement in fit to the data over a unidimensional representation of expectancy-value attitude.

The test of this analysis involved the comparison of nested models (see Figure 4, p. 138). Specifically, the unidimensional representation of expectancy-value attitude is a model nested within the two-dimensional representation. Thus, the analysis consisted of using LISREL VII to fit the data independently to the unidimensional and two-dimensional models. The chi-square difference test was used to determine whether the two-factor model fit the data significantly better than the one-factor model. However, other overall descriptive measures of fit (e.g. TLI, PNFI, RNFI) contributed to comparing and evaluating the alternative models.
Research question 2. The second research question addressed the structure, or underlying dimensional nature, of the normative belief-motivation to comply composite within the Theory of Planned Behavior. Specifically, this investigation proposed that a two-dimensional rather than a unidimensional structure is a better representation of this construct. This proposition is tested in Hypothesis 2.1.

H2.1: A two-dimensional model of the normative belief-motivation to comply (NBMC) composite in which one dimension represents 'authoritative' and the other represents 'nonauthoritative' referents will provide a significant improvement in fit to the data over a unidimensional representation of the NBMC composite.

The test of this hypothesis was identical to the test for the previous hypothesis. That is, since the unidimensional representation of the NBMC composite is nested within the two-dimensional representation, the chi-square difference test was an appropriate one. Again, other descriptive measures of fit assisted in comparing the alternative models.

Research question 3. The third research question addressed the antecedent of perceived behavioral control. Specifically, the question proposed that an antecedent consisting of a composite of control beliefs and the strength of their influence is a better representation of the perceived behavioral control construct than a set of 'control beliefs' as proposed by Ajzen and his colleagues. The test of this research question is provided with Hypothesis 3.1.
H3.1: An antecedent of perceived behavioral control that is represented as a control belief-strength of influence (CBSI) composite will provide a significant improvement in fit to the data over an antecedent that is represented as a component consisting only of control beliefs (CB).

The test of this hypothesis differed from the test used in the previous two hypotheses in that the composite and the CB representations of the antecedent of perceived behavioral control are not nested models (see Figure 6, p. 157). Although CB is a component of the CBSI composite, the measured variables of CB were derived from scores on the belief scales whereas the measured variables, or indicators, for the CBSI composite were product terms (i.e. score from control belief scale times score from strength of influence scale). Thus, the parameters of one model were not a subset of another model's parameters and these models could not be inferentially compared with the chi-square difference test. That is, this hypothesis was not statistically testable.

As previously described, when comparing models that are not nested, the model with the smaller chi-square generated from a LISREL analysis is preferred. However, its presumed advantage in fitting the data must be balanced with its loss in parsimony and therefore, other descriptive measures of fit such as TLI, PNFI, and RNFI, were useful in comparing these alternative models.

Research question 4. The fourth research question addressed the structure, or underlying dimensional nature, of the antecedent of perceived behavioral control. Specifically, the question proposed that the antecedent of perceived behavioral control, whether it is a composite or a component consisting of control beliefs, was
better represented as a two-dimensional rather than a unidimensional structure. The test of this research question is provided in Hypotheses 4.1 and 4.2.

**H4.1:** A two-dimensional model of the control belief-strength of influence (CBSI) composite in which one dimension represents 'internal control factors' and the other represents 'external control factors' will provide a significant improvement in fit to the data over a unidimensional representation of the CBSI composite.

**H4.2:** A two-dimensional model of the control belief (CB) construct in which one dimension represents 'internal control factors' and the other represents 'external control factors' will provide a significant improvement in fit to the data over a unidimensional representation of the CB construct.

The test of these two hypotheses involved inferentially comparing two sets of nested models: a unidimensional representation of CBSI nested within a two-dimensional representation (see Figure 7, p. 165) and a unidimensional representation of CB nested within its two-dimensional representation (see Figure 8, p. 167). Therefore, LISREL independently fit the data to the two sets of models. The chi-square difference test provided an inferential test of whether or not the two-factor CBSI and CB models fit the data significantly better than the one-factor CBSI and CB models, respectively. Again, other descriptive measures of overall fit were useful in comparing the unidimensional representations to the two-dimensional representations of both constructs.
Research questions 5 through 7. Research questions 5 through 7 compared the models of interest in this investigation. To test the hypotheses for these research questions, a series of seven nested models were proposed (see Figure 15). The modeling approach used in this investigation to compare these models has been previously described. In short, a total of eleven nested models obtained from a single covariance matrix were estimated: (1) the null model; (2) the uncorrelated factors model; (3-9) the models of interest in this investigation including TRA, MTRA-1, TPB, MTPB-1, MTPB-1a, MTPB-2, and MTPB-3; (10) the measurement model; and (11) the "just identified" or "saturated" model. Similar to the work of Bentler and Speckart (1981), Fredricks and Dossett (1983), and Netemeyer et. al. (1991), this investigation included all exogenous variables' correlation in estimating models' parameters. Since the focus of the proposed hypotheses was the improvement of fit due to one given parameter (e.g. PBC--- > BI for the TPB; ATT_o-- > BI for the MTPB-2, etc.), any improvement in fit due to the estimation of correlation parameters must be evaluated before assessing the improvement of fit due to the hypothesized parameter. This approach prevented the biasing of fit statistics against the models nested within the MTPB-3.

The indices generated and calculated from the LISREL's estimation of the models' parameters that were used to compare the models included: chi-square, Tucker Lewis Index (TLI), Type 2 parsimonious normed-fit index [PNFI(2)], and Type 2 relative normed-fit index [RNFI(2)]. Although the chi-square difference test was used to select the best fitting model from the sets of two models proposed, other descriptive indices of the model's overall fit to the data assisted in the comparison process.
The modeling approach taken in this investigation aimed to identify the most appropriate model, in terms of its goodness of fit and parsimony. Upon completing the parameter estimation of the series of nested models, the following hypotheses had been tested:

**H5.1:** The Theory of Planned Behavior (TPB) will provide a significant improvement in fit to the data over the Theory of Reasoned Action (TRA).

**H6.2.1:** A modified model of the Theory of Planned Behavior in which past behavior directly impacts behavioral intention (MTPB-1) will provide a significant improvement in fit to the data over the Theory of Planned Behavior (TPB).

**H6.2.2:** A modified model of the Theory of Planned Behavior in which past behavior directly impacts attitude and behavioral intention (MTPB-1a) will not provide a significant improvement in fit to the data over the modified model in which past behavior directly impacts only behavioral intention (MTPB-1).

**H6.3:** A modified model of the Theory of Planned Behavior in which past behavior directly impacts behavioral intention (MTPB-1) will provide a significant improvement in fit to the data over the modified model of the Theory of Reasoned Action in which past behavior directly impacts behavioral intention (MTRA-1).

**H7.1:** A modified model of the Theory of Planned Behavior in which physicians' attitude toward the FDA directly impacts their intention to report adverse drug events to the FDA (MTPB-2) will provide a significant improvement in fit to the data over the Theory of Planned Behavior (TPB).
H7.2: A modified model of the Theory of Planned Behavior in which both physicians' attitude toward the FDA and their past reporting behavior impact their intention to report adverse drug events to the FDA (MTPB-3) will provide a significant improvement in fit to the data over the modified model of the Theory of Planned Behavior in which physicians' past reporting behavior directly impacts behavioral intention (MTPB-1).

H7.3: A modified model of the Theory of Planned Behavior in which both physicians' attitude toward the FDA and their past reporting behavior impact their intention to report adverse drug events to the FDA (MTPB-3) will provide a significant improvement in fit to the data over the modified model of the Theory of Planned Behavior in which physicians' attitude toward the FDA directly impacts behavioral intention (MTPB-2).

One final hypothesis, Hypothesis 6.1, is addressed in estimating the models that include past behavior as a determinant of physicians' behavioral intention. The significance of the frequency and recency indicators is determined by the 't-statistic', the ratio of estimated parameter to its standard error, that is generated during a LISREL analysis.

H6.1: Both frequency (F) and recency (R) are significant indicators of physicians' past reporting of serious adverse drug events to the FDA.
Panel A: Theory of Reasoned Action (TRA)

\[
\begin{align*}
\text{ATT} & \quad \text{BI} \\
\text{GSN} & \quad \text{BI}
\end{align*}
\]

Panel B: Modified Theory of Reasoned Action (MTRA-1)

\[
\begin{align*}
\text{ATT} & \quad \text{BI} \\
\text{GSN} & \quad \text{BI} \\
\text{PB} & \quad \text{BI}
\end{align*}
\]

Panel C: Theory of Planned Behavior (TPB)

\[
\begin{align*}
\text{ATT} & \quad \text{BI} \\
\text{GSN} & \quad \text{BI} \\
\text{PBC} & \quad \text{BI}
\end{align*}
\]

Panel D: Modified Theory of Planned Behavior (MTPB-1)

\[
\begin{align*}
\text{ATT} & \quad \text{BI} \\
\text{GSN} & \quad \text{BI} \\
\text{PB} & \quad \text{BI} \\
\text{PBC} & \quad \text{BI}
\end{align*}
\]

Figure 15*: Models for Research Questions 5 to 7

* For diagrammatic simplicity, the proposed correlations between all determinants of BI are omitted.
Figure 15 (continued)

Panel E: Modified Theory of Planned Behavior (MTPB-1a)

Panel F: Modified Theory of Planned Behavior (MTPB-2)

Panel G: Modified Theory of Planned Behavior (MTPB-3)
CHAPTER IV
RESULTS AND DISCUSSION

The objective of this chapter is to present and discuss the results of the research questions and their hypotheses. First, however, this chapter briefly discusses pertinent characteristics of the study data. The results and their discussion are then presented in three sections. The first section provides the results of the submodels analyses, i.e. Research Questions 1 to 4. The second section presents the results of testing the series of nested models developed and proposed in Chapters II and III, Research Questions 5 to 7. Finally, results obtained from and discussion regarding this investigation's specification search are provided.

Characteristics of the Study Data

The primary objective of examining the study data was to assess its distribution, specifically, its multivariate normality. This step was necessary to assure that the assumption of multivariate normality required for estimating parameters with the maximum likelihood technique was not severely violated. The objective was met by using PRELIS (1986) to provide univariate statistics for each measured variable and an overall measure of multivariate kurtosis. These statistics were generated for two sets of data: (1) data used in the overall intention model including the CB construct and (2) data used in the overall model including the CBSI construct.
The univariate statistics generated from the PRELIS (1986) analysis indicated that 92% of the study participants had not previously reported a serious adverse drug event during the prior two years. Thus, the distribution of the 'frequency' and 'recency' measures were highly skewed to the right, rendering it impossible to obtain any measure of past behavior. Consequently, the 'past behavior' construct included in some models proposed in Chapter II (MTRA-1, MTPB-1, MTPB-1a, MTPB-3) and their associated hypotheses (H6.1, H6.2.1, H6.2.2, H6.3, H7.2) were dropped from the investigation's data analysis.

After deleting the measures of past behavior, the PRELIS (1986) program was used to generate multivariate kurtosis coefficients for the two sets of data (i.e. CB and CBSI data sets). These analyses yielded coefficients of 1.32 and 1.29 for the CB and CBSI data sets, respectively. According to Cudeck and Browne (1983), these values are not greatly inconsistent with the assumption of multivariate normality.

The PRELIS program can adjust the distribution of the measured variables toward greater normality (referred to as 'censored' data). Multivariate kurtosis coefficients obtained from 'censoring' the CBSI and CB data sets were 1.28 and 1.27, respectively. This investigation opted to use 'uncensored' data sets because: (1) little difference existed between the 'uncensored' and 'censored' data sets, in terms of multivariate kurtosis coefficients, (2) the value of multivariate kurtosis for the 'uncensored' data was not discordant with the multivariate normality assumption required for the use of the MLE and (3) adjusting the distribution of the measured variables prior to analyses may have introduced questions regarding the validity of inferentially testing the proposed set of nested models. The correlation matrices used for data input for the CBSI and CB data sets are provided in Appendix E.
Results of the Submodel Analyses

The objective of the first two research questions proposed in Chapter II was to determine the structure of expectancy-value attitude (EV) and the normative belief-motivation to comply composite (NBMC). The next two research questions addressed the antecedent of perceived behavioral control (PBC) and the structure underlying its determinants. The results of testing the hypotheses proposed for each research question are summarized in Tables 8 and 9. Specifically, Table 8 presents the overall measures of fit used to inferentially and descriptively compare each unidimensional submodel with its corresponding two-dimensional representation; Table 9 provides the results of the chi-square difference tests. The following section discusses the results of each research question and presents further information regarding the submodels' structure.

RO 1: Structure of Expectancy-Value Attitude

The first research question sought to determine whether this study's results supported previously conducted research with the Theory of Reasoned Action finding that the antecedent of attitude toward the behavior, i.e. expectancy-value attitude, is better represented as a two-dimensional rather than a unidimensional structure. This question was posed and tested in Hypothesis 1.1.

H1.1: A two-dimensional model of expectancy-value attitude in which one dimension represents the positive and the other represents the negative consequences of reporting a serious ADE to the FDA will provide a significant improvement in fit to the data over a unidimensional representation of expectancy-value attitude.
Table 8

<table>
<thead>
<tr>
<th>Submodel</th>
<th>Chi-square</th>
<th>df</th>
<th>RMSR</th>
<th>GFI</th>
<th>PGFI(1)</th>
<th>TLI</th>
<th>PNFI(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EV</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Null</td>
<td>2602.06</td>
<td>91</td>
<td>.289</td>
<td>.445</td>
<td>.386</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>Uni-D</td>
<td>519.82</td>
<td>75</td>
<td>.091</td>
<td>.874</td>
<td>.624</td>
<td>.785</td>
<td>.679</td>
</tr>
<tr>
<td>Two-D</td>
<td>510.45</td>
<td>73</td>
<td>.089</td>
<td>.872</td>
<td>.605</td>
<td>.783</td>
<td>.663</td>
</tr>
<tr>
<td><strong>NBMC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Null</td>
<td>3036.85</td>
<td>45</td>
<td>.404</td>
<td>.358</td>
<td>.293</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>Uni-D</td>
<td>543.46</td>
<td>34</td>
<td>.127</td>
<td>.848</td>
<td>.520</td>
<td>.775</td>
<td>.627</td>
</tr>
<tr>
<td>Two-D</td>
<td>351.66</td>
<td>32</td>
<td>.142</td>
<td>.895</td>
<td>.514</td>
<td>.850</td>
<td>.635</td>
</tr>
<tr>
<td><strong>CB</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Null</td>
<td>3050.03</td>
<td>66</td>
<td>.365</td>
<td>.366</td>
<td>.310</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>Uni-D</td>
<td>749.52</td>
<td>52</td>
<td>.111</td>
<td>.766</td>
<td>.511</td>
<td>.703</td>
<td>.605</td>
</tr>
<tr>
<td>Two-D</td>
<td>745.43</td>
<td>50</td>
<td>.111</td>
<td>.770</td>
<td>.494</td>
<td>.692</td>
<td>.582</td>
</tr>
<tr>
<td><strong>CBSI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Null</td>
<td>2825.64</td>
<td>66</td>
<td>.348</td>
<td>.388</td>
<td>.328</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>Uni-D</td>
<td>661.25</td>
<td>52</td>
<td>.104</td>
<td>.796</td>
<td>.531</td>
<td>.720</td>
<td>.615</td>
</tr>
<tr>
<td>Two-D</td>
<td>545.81</td>
<td>50</td>
<td>.104</td>
<td>.848</td>
<td>.544</td>
<td>.763</td>
<td>.622</td>
</tr>
</tbody>
</table>

Uni-D = Unidimensional structure
Two-D = Two-dimensional structure

a - Equations for calculating PGFI(1), TLI, and PNFI(2) are found in Chapter III, pp. 251-252.
Table 9

SUBMODELS: CHI-SQUARE DIFFERENCE TESTS

<table>
<thead>
<tr>
<th>Submodels</th>
<th>Differences in:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chi-square</td>
<td>df</td>
<td>Probability</td>
</tr>
<tr>
<td><strong>EV</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Uni-D vs Null</td>
<td>2082.24</td>
<td>15</td>
<td>&lt; .000</td>
</tr>
<tr>
<td>*Two-D vs Uni-D</td>
<td>9.37</td>
<td>2</td>
<td>&lt; .01</td>
</tr>
<tr>
<td><strong>NBMC</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Uni-D vs Null</td>
<td>2493.40</td>
<td>11</td>
<td>&lt; .000</td>
</tr>
<tr>
<td>*Two-D vs Uni-D</td>
<td>191.80</td>
<td>2</td>
<td>&lt; .001</td>
</tr>
<tr>
<td><strong>CB</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Uni-D vs Null</td>
<td>2300.51</td>
<td>14</td>
<td>&lt; .000</td>
</tr>
<tr>
<td>Two-D vs Uni-D</td>
<td>4.09</td>
<td>2</td>
<td>n.s.</td>
</tr>
<tr>
<td><strong>CBSI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Uni-D vs Null</td>
<td>2164.39</td>
<td>14</td>
<td>&lt; .000</td>
</tr>
<tr>
<td>*Two-D vs Uni-D</td>
<td>115.44</td>
<td>2</td>
<td>&lt; .001</td>
</tr>
<tr>
<td><strong>CBSI vs CB</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Uni-D (CBSI) vs Uni-D (CB)</td>
<td>88.27</td>
<td>0</td>
<td>**</td>
</tr>
<tr>
<td>*Two-D (CBSI) vs Two-D (CB)</td>
<td>199.62</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Uni-D = Unidimensional structure  
Two-D = Two-dimensional structure

* - Model fitting the sample data significantly better
** - Not statistically testable
The results from fitting the study data to the expectancy-value submodel represented as unidimensional and two-dimensional structures, along with the results obtained from the null model, are provided in Table 8. Both the unidimensional and two-dimensional representations of the EV composite substantially decreased the chi-square value obtained with the null model. In addition, both structures decreased the RMSR and increased the overall goodness-of-fit measures. Closer examination of the fit measures suggest that while the RMSR, GFI, and TLI for the two-dimensional model is relatively equal to the unidimensional structure, the unidimensional outperforms the two-dimensional representation for fit measures that are adjusted for the model's parsimony, PGFI(1) and PNFI(2).

Table 9 provides the results of the chi-square difference test used to inferentially select the submodel best fitting the data. As expected, the unidimensional representation fit the data significantly better than the null model (p < .000). In addition, the table indicates that the two-dimensional representation of expectancy-value attitude fit the data significantly better than the unidimensional structure (p < .01). Therefore, although the descriptive measures of fit provide an unclear comparison of the two representations of the EV composite, the inferential chi-square difference test indicates that the composite is better represented as a multi-dimensional rather than a unidimensional structure, thus supporting Hypothesis 1.1

Finally, Table 10 provides structural parameter estimates of the two-dimensional expectancy-value submodel as well as information regarding the discriminant validity of EV(+) and EV(-). As expected, physicians' positive belief-evaluations positively and significantly impacted their attitude toward reporting serious adverse drug events to the FDA (p < .001). In addition, their negative belief-evaluations had a negative but insignificant impact on their attitudes. The correlation between
Table 10

EXPECTANCY-VALUE TWO-DIMENSIONAL SUBMODEL: 
STRUCTURAL PARAMETER ESTIMATES

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Estimate (Standard error)</th>
<th>Standardized estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATT → BI: $\beta_{12}$</td>
<td>.830 (.077)</td>
<td>.615$^a$</td>
</tr>
<tr>
<td>EV(+) → ATT: $\gamma_{21}$</td>
<td>.648 (.201)</td>
<td>.933$^a$</td>
</tr>
<tr>
<td>EV(-) → ATT: $\gamma_{22}$</td>
<td>-.193 (.203)</td>
<td>-.277$^b$</td>
</tr>
<tr>
<td>EV(-) &lt; EV(+): $\phi_{21}$</td>
<td>.888 (.050)</td>
<td>.888$^a$</td>
</tr>
</tbody>
</table>

$^a$ - $p < .001$

$^b$ - not significant
EV(+) and EV(-) was relatively high, suggesting a lack of discriminant validity between the two composites (p < .001). However, an examination of the correlation's confidence intervals indicated that this correlation was significantly less than 1.0 (p < .05).

**RQ 2: Structure of the NBMC Composite**

The second research question aimed to determine whether the data obtained in this investigation would support previous research conducted with the TRA finding that the normative belief-motivation to comply composite determining subjective norm existed as a multi-dimensional rather than a unidimensional structure. This proposition was tested with Hypothesis 2.1.

**H2.1:** A two-dimensional model of the normative belief-motivation to comply (NBMC) composite in which one dimension represents 'authoritative' and the other represents 'nonauthoritative' referents will provide a significant improvement in fit to the data over a unidimensional representation of the NBMC composite.

The results of testing this hypothesis supported the two-dimensional representation of the NBMC composite over the unidimensional representation. As indicated in Table 9, the chi-square difference test indicated that the study data fit the unidimensional submodel significantly better than the null model (p < .000). Furthermore, the data fit the two-dimensional submodel significantly better than the composite's unidimensional representation (p < .001). Although the descriptive measures of overall fit varied in their support of the unidimensional versus two-dimensional submodels, the TLI measure of overall fit, one of the indices preferred
in this investigation, supported the two-dimensional submodel. Therefore, this investigation's data analysis supported Hypothesis 2.1.

The structural parameter estimates of the two-dimensional normative belief-motivation to comply submodel are provided in Table 11. Physicians' perceptions about the social pressures put on them to report or to not report a serious adverse drug event to the FDA was a significant predictor of their intentions to report (p < .001). In terms of specific normative referents, the referents belonging to the 'nonauthoritative' group significantly predicted GSN (p < .001) whereas those belonging to the 'authoritative' group were not significant predictors. Finally, the correlation between authoritative and nonauthoritative NBMC was significant (p < .001). However, this correlation was significantly less than 1.0, thus supporting the discriminant validity of the two-factor model (p < .001).

**RO 3: Antecedent of Perceived Behavioral Control**

The third research question addressed whether the antecedent of perceived behavioral control was better represented as a set of beliefs pertaining to the physician's control over reporting a serious adverse drug event to the FDA or as a composite consisting of these control beliefs multiplied by their strength of influence over performing the behavior. Hypothesis 3.1 was proposed to answer this research question.

**H3.1** An antecedent of perceived behavioral control that is represented as a control belief-strength of influence (CBSI) composite will provide a significant improvement in fit to the data over an antecedent that is represented as a component consisting only of control beliefs (CB).
Table 11

NORMATIVE BELIEF-MOTIVATION TO COMPLY TWO-DIMENSIONAL SUBMODEL:
STRUCTURAL PARAMETER ESTIMATES

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Estimate (Standard error)</th>
<th>Standardized estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>GSN→BI: ( \beta_{12} )</td>
<td>.201 (.045)</td>
<td>.206&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>NBMC&lt;sub&gt;A&lt;/sub&gt;→GSN: ( \gamma_{21} )</td>
<td>.046 (.055)</td>
<td>.046&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>NBMC&lt;sub&gt;NA&lt;/sub&gt;→GSN: ( \gamma_{22} )</td>
<td>.599 (.058)</td>
<td>.599&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>NBMC&lt;sub&gt;NA&lt;/sub&gt;&lt;---NBMC&lt;sub&gt;A&lt;/sub&gt;: ( \phi_{21} )</td>
<td>.665 (.030)</td>
<td>.665&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup> p < .001
<sup>b</sup> not significant
As discussed in Chapter III, the two submodels proposed as the antecedent of perceived behavioral control consist of different sets of measured variables and thus, are alternative but not nested models. Consequently, these models can not be inferentially compared, i.e. the hypothesis is not statistically testable. However, the same measures of overall goodness-of-fit used to test the first two hypotheses and evaluate the submodels are used to select the submodel of perceived behavioral control that best fits this study's data.

In comparing the unidimensional CB submodel with the unidimensional CBSI submodel and the two-dimensional CB submodel with the two-dimensional CBSI submodel, Tables 8 and 9 indicate that for both dimensional representations, the chi-squares attained with the CBSI submodel (unidimensional = 661.25, 52 df; two-dimensional = 545.81, 50 df) are substantially less than those obtained from analyses with the CB submodel (unidimensional = 747.52, 52 df; two-dimensional = 745.43, 50 df). In addition, all descriptive measures of overall fit indicate that the antecedent of perceived behavioral control is better represented with the CBSI submodel than the CB submodel. Since the chi-squares of the CBSI submodel is substantially smaller than those of the CB submodel with the same number of degrees of freedom (for both the unidimensional and two-dimensional representations), and the other descriptive measures of overall model fit support this finding, this investigation selected the CBSI submodel to include in the analyses of the overall models proposed in Chapter II.
RQ 4: Structure of PBC's Antecedent

The fourth research question addressed the structure of the antecedent of perceived behavioral control. This question posed a two-dimensional structure for both the CB and the CBSI submodels which were tested with Hypotheses 4.1 and 4.2.

H4.1: A two-dimensional model of the control belief-strength of influence (CBSI) composite in which one dimension represents 'internal control factors' and the other represents 'external control factors' will provide a significant improvement in fit to the data over a unidimensional representation of the CBSI composite.

H4.2: A two-dimensional model of the control belief (CB) construct in which one dimension represents 'internal control factors' and the other represents 'external control factors' will provide a significant improvement in fit to the data over a unidimensional representation of the CB construct.

The chi-square difference tests provided in Table 9 indicate that the two-dimensional representation of the CBSI submodel fit the study data significantly better than the composite's unidimensional representation ($p < .001$). The descriptive measures of fit provided in Table 8 support this finding in that both Type I and Type 2 goodness-of-fit indices were higher for the two-factor model than the one-factor model. Therefore, this investigation's data analysis supported Hypothesis 4.1.

In terms of the structure of the proposed CB submodel, a two-factor model did not significantly improve the fit of the model to the study data over a one-factor
model, thus failing to support Hypothesis 4.2 (See Table 9). This finding is also supported in descriptive measures of overall model fit provided in Table 8. Since the CBSI submodel performed better than the CB submodel, however, the lack of support for the two-factor CB model is not a concern.

Table 12 provides the structural parameter estimates of the CBSI submodel. Physicians' perceived control over reporting a serious adverse drug event to the FDA was a significant predictor of their intention to report or to not report (p < .001). In addition, factors classified as 'internal' and 'external' to the physician significantly impacted their perception of control (p < .001). Although the correlation between these two factors was relatively high, it was significantly less than 1.0 (p < .001). Thus, the discriminant validity of the two-dimensional CBSI submodel was supported in this investigation.

**Summary of Submodel Analyses**

The results from testing the hypotheses proposed in the first four research questions supported:

(1) a two-dimensional representation of expectancy-value attitude rather than a unidimensional representation. One dimension represented positive belief-evaluations regarding reporting a serious adverse drug event to the FDA and the other represented negative belief-evaluations.

(2) a two-dimensional representation of the normative-belief motivation to comply composite rather than a unidimensional structure. One dimension represented referents that could be classified as 'authoritative' and the other dimension could be classified as 'nonauthoritative' referents with respect to physicians' professional practice.
Table 12

CONTROL BELIEF-STRENGTH OF INFLUENCE TWO-DIMENSIONAL SUBMODEL:
STRUCTURAL PARAMETER ESTIMATES

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Estimate (Standard error)</th>
<th>Standardized estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBC→BI: ( \beta_{12} )</td>
<td>1.112 (.085)</td>
<td>.726(^{a})</td>
</tr>
<tr>
<td>CBSI(<em>{1})→PBC: ( \gamma</em>{21} )</td>
<td>.421 (.041)</td>
<td>.676(^{a})</td>
</tr>
<tr>
<td>CBSI(<em>{2})→PBC: ( \gamma</em>{22} )</td>
<td>.299 (.039)</td>
<td>.479(^{a})</td>
</tr>
<tr>
<td>CBSI(<em>{2})→CBSI(</em>{1}): ( \phi_{21} )</td>
<td>.609 (.042)</td>
<td>.609(^{a})</td>
</tr>
</tbody>
</table>

\(^{a}\) - \( p < .001 \)
(3) an antecedent of perceived behavioral control that was better represented as a composite of control beliefs and their corresponding strength of influence on physicians' perception of control over their reporting rather than solely a set of beliefs about control.

(4) a two-dimensional representation of the control belief-strength of influence composite over a unidimensional representation of the composite. One dimension represented factors internal to the physician that impacted his perception of control over reporting and the other dimension represented factors external to the physician impacting his perception of control.

The submodels incorporated in the overall model of physicians' reporting intentions, therefore, included the two-dimensional representation of the EV, NBMC and CBSI composites.

Results of the Overall Model Analyses

The objective of the remaining research questions was to evaluate and compare the models of interest in this investigation. A series of seven nested models was proposed in Chapter II and readdressed in Chapter III (see pp. 271-272). This series included: the Theory of Reasoned Action (TRA); one modified version of the Theory of Reasoned Action (MTRA-1); the Theory of Planned Behavior (TPB); and four modified versions of the Theory of Planned Behavior (MTPB-1, MTPB-1a, MTPB-2, MTPB-3). Due to the infrequency of physicians' past reporting behavior and the subsequent deletion of this variable from the proposed model depicting physicians' reporting intentions, the hypotheses and the models proposed which
included past behavior as a predictor of behavioral intention were not able to be tested.

The following sections present the results from estimating and comparing the series of remaining nested models. These include: the Theory of Reasoned Action; the Theory of Planned Behavior; and the modified version of the Theory of Planned Behavior in which 'attitude toward the FDA' is proposed as an independent predictor of physicians' reporting intentions. The other four models included in the series were the null model, the uncorrelated factors model, the measurement model, and the 'saturated' or 'just-identified' model.

The first section discusses the measurement properties of the indicators of the overall model's constructs. Next, the results are discussed in terms of empirical support for the three models as well as their absolute and relative representation of the study data. Finally, the completion of the first two sections provides the information needed to summarize the results of the remaining research hypotheses.

**Measurement Properties of Observed Variables**

Tables 13 and 14 contain the measurement properties of the observed variables used to measure the constructs included in the overall reporting model. These measurement statistics were generated from the estimation of the 'measurement' model, as recommended by Anderson and Gerbing (1988) and Netemeyer et. al. (1991).

As previously discussed, the advantage of employing covariance structure modeling to calculate a scale's reliability is that the validity of the individual items can be assessed because the technique does not assume equal item reliability as is the case with coefficient alpha. Table 13 clearly demonstrates that while some of the
### Table 13

**OVERALL MODEL: MEASUREMENT PROPERTIES OF OBSERVED VARIABLES**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Item</th>
<th>Lamda (factor loading)</th>
<th>Item Reliability</th>
<th>Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>$y_1$</td>
<td>$I_1$</td>
<td>.946</td>
<td>.894</td>
<td>.106</td>
</tr>
<tr>
<td>$y_2$</td>
<td>$I_2$</td>
<td>.939</td>
<td>.881</td>
<td>.119</td>
</tr>
<tr>
<td>$y_3$</td>
<td>$A_{B1}$</td>
<td>.698</td>
<td>.488</td>
<td>.512</td>
</tr>
<tr>
<td>$y_4$</td>
<td>$A_{B2}$</td>
<td>.728</td>
<td>.530</td>
<td>.470</td>
</tr>
<tr>
<td>$y_5$</td>
<td>$A_{B3}$</td>
<td>.600</td>
<td>.360</td>
<td>.640</td>
</tr>
<tr>
<td>$y_6$</td>
<td>$A_{B4}$</td>
<td>.698</td>
<td>.487</td>
<td>.513</td>
</tr>
<tr>
<td>$y_7$</td>
<td>SNMC$^a$</td>
<td>1.0</td>
<td>1.0</td>
<td>0</td>
</tr>
<tr>
<td>$y_8$</td>
<td>GC$_1$</td>
<td>.784</td>
<td>.615</td>
<td>.85</td>
</tr>
<tr>
<td>$y_9$</td>
<td>GC$_2$</td>
<td>.481</td>
<td>.231</td>
<td>.769</td>
</tr>
<tr>
<td>$y_{10}$</td>
<td>GC$_3$</td>
<td>.063</td>
<td>.004</td>
<td>.996</td>
</tr>
<tr>
<td>$y_{11}$</td>
<td>GC$_4$</td>
<td>.126</td>
<td>.016</td>
<td>.984</td>
</tr>
<tr>
<td>$x_1$</td>
<td>BE$_1$</td>
<td>.680</td>
<td>.463</td>
<td>.537</td>
</tr>
<tr>
<td>$x_2$</td>
<td>BE$_2$</td>
<td>.432</td>
<td>.186</td>
<td>.814</td>
</tr>
<tr>
<td>$x_3$</td>
<td>BE$_3$</td>
<td>.585</td>
<td>.342</td>
<td>.658</td>
</tr>
<tr>
<td>$x_4$</td>
<td>BE$_4$</td>
<td>.721</td>
<td>.520</td>
<td>.480</td>
</tr>
<tr>
<td>$x_5$</td>
<td>BE$_5$</td>
<td>.280</td>
<td>.078</td>
<td>.922</td>
</tr>
</tbody>
</table>

*Values given for standardized variables obtained from measurement model.

---

* a - since SNMC is a one-item indicator of GSN, there is no error in the measure. Estimating the item's error in the overall intention showed the reliability and error of the measure to equal .618 and .382, respectively.
Table 13 (continued)

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Item</th>
<th>Lamda_1 (factor loading)</th>
<th>Item Reliability</th>
<th>Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>x_6</td>
<td>BE_6</td>
<td>.766</td>
<td>.587</td>
<td>.413</td>
</tr>
<tr>
<td>x_7</td>
<td>BE_7</td>
<td>.876</td>
<td>.768</td>
<td>.232</td>
</tr>
<tr>
<td>x_8</td>
<td>BE_8</td>
<td>.200</td>
<td>.040</td>
<td>.960</td>
</tr>
<tr>
<td>x_9</td>
<td>NM_1</td>
<td>.543</td>
<td>.295</td>
<td>.705</td>
</tr>
<tr>
<td>x_{10}</td>
<td>NM_2</td>
<td>.919</td>
<td>.845</td>
<td>.155</td>
</tr>
<tr>
<td>x_{11}</td>
<td>NM_3</td>
<td>.906</td>
<td>.821</td>
<td>.178</td>
</tr>
<tr>
<td>x_{12}</td>
<td>NM_4</td>
<td>.922</td>
<td>.850</td>
<td>.150</td>
</tr>
<tr>
<td>x_{13}</td>
<td>NM_5</td>
<td>.860</td>
<td>.740</td>
<td>.261</td>
</tr>
<tr>
<td>x_{14}</td>
<td>NM_6</td>
<td>.733</td>
<td>.537</td>
<td>.463</td>
</tr>
<tr>
<td>x_{15}</td>
<td>NM_7</td>
<td>.160</td>
<td>.026</td>
<td>.974</td>
</tr>
<tr>
<td>x_{16}</td>
<td>CS_1</td>
<td>.758</td>
<td>.575</td>
<td>.425</td>
</tr>
<tr>
<td>x_{17}</td>
<td>CS_2</td>
<td>.879</td>
<td>.773</td>
<td>.227</td>
</tr>
<tr>
<td>x_{18}</td>
<td>CS_3</td>
<td>.645</td>
<td>.417</td>
<td>.583</td>
</tr>
<tr>
<td>x_{19}</td>
<td>CS_4</td>
<td>.559</td>
<td>.312</td>
<td>.688</td>
</tr>
<tr>
<td>x_{20}</td>
<td>CS_5</td>
<td>.736</td>
<td>.541</td>
<td>.459</td>
</tr>
<tr>
<td>x_{21}</td>
<td>CS_6</td>
<td>.709</td>
<td>.503</td>
<td>.497</td>
</tr>
<tr>
<td>x_{22}</td>
<td>A_{01}</td>
<td>.742</td>
<td>.550</td>
<td>.450</td>
</tr>
<tr>
<td>x_{23}</td>
<td>A_{02}</td>
<td>.712</td>
<td>.506</td>
<td>.494</td>
</tr>
<tr>
<td>x_{24}</td>
<td>A_{03}</td>
<td>.752</td>
<td>.566</td>
<td>.434</td>
</tr>
<tr>
<td>x_{25}</td>
<td>A_{04}</td>
<td>.599</td>
<td>.359</td>
<td>.641</td>
</tr>
</tbody>
</table>
Table 14
OVERALL MODEL: MEASUREMENT PROPERTIES OF CONSTRUCTS

<table>
<thead>
<tr>
<th>Construct</th>
<th>Number of indicators</th>
<th>Composite(^a) reliability</th>
<th>Variance(^a) extracted</th>
</tr>
</thead>
<tbody>
<tr>
<td>BI</td>
<td>2</td>
<td>.940</td>
<td>.888</td>
</tr>
<tr>
<td>ATT</td>
<td>4</td>
<td>.777</td>
<td>.466</td>
</tr>
<tr>
<td>GSN</td>
<td>1</td>
<td>1.0(^b)</td>
<td>1.0(^b)</td>
</tr>
<tr>
<td>PBC</td>
<td>4</td>
<td>.403</td>
<td>.212</td>
</tr>
<tr>
<td>EV (+)</td>
<td>4</td>
<td>.701</td>
<td>.378</td>
</tr>
<tr>
<td>EV (-)</td>
<td>4</td>
<td>.641</td>
<td>.368</td>
</tr>
<tr>
<td>NBMC(_A)</td>
<td>4</td>
<td>.844</td>
<td>.654</td>
</tr>
<tr>
<td>NBMC(_NA)</td>
<td>4</td>
<td>.795</td>
<td>.538</td>
</tr>
<tr>
<td>CBSI(_I)</td>
<td>3</td>
<td>.808</td>
<td>.588</td>
</tr>
<tr>
<td>CBSI(_E)</td>
<td>3</td>
<td>.710</td>
<td>.452</td>
</tr>
<tr>
<td>ATT(_O)</td>
<td>4</td>
<td>.796</td>
<td>.494</td>
</tr>
</tbody>
</table>

\(a\) - Equations for calculating are found in Chapter III, p. 230

\(b\) - since SNMC is a one-item indicator of GSN, there is no error in the measure, i.e. perfect reliability of the construct and total variance extracted. Freeing the error term in estimating the overall intention model indicated that both the composite's reliability and variance extracted were .618.
indicators were reliable measures of the constructs they purportedly represented, others measures contained a large amount of unexplained variance, or error. Items that were highly unreliable were identified in nearly all of the constructs included in the measurement model.

The significance in recognizing the unreliability of indicators used in this investigation is demonstrated in Table 14. Specifically, Table 14 presents the number of indicators used to measure each construct, the construct's or composite's reliability, and the amount of variance captured by the construct from its indicators. The composite reliability and the amount of variance extracted by the construct are calculated from the factor loadings, item reliabilities, and errors of indicators provided in Table 13. Therefore, the unreliability of individual items is reflected in the construct's overall reliability and the amount of extracted variance.

As previously explained, the 'amount of variance extracted' by a construct is a more conservative estimate than its overall reliability (Fornell and Larcker, 1981). While the composite reliability may appear adequate (i.e. .70), the amount of variance extracted by the construct may indicate that more than half of the variance is due to measurement error. Fornell and Larcker recommend that if the amount of variance extracted is less than .50 (i.e. the amount of error is larger than the amount of explained variance) the validity of the individual indicators as well as the construct is questionable.

Many of the composite reliabilities found in this investigation appeared adequate (> .70), according to the standards of basic research set by Nunnally (1978). The PBC and EV(-) composites attained the lowest overall reliability of .403 and .641, respectively. The composite reliabilities for EV(+) and CBSI_E are borderline at
.701 and .710, respectively. These values are not surprising since some of the individual indicators for these constructs were unreliable (See Table 15).

In terms of the amount of variance extracted by the constructs, five out of eleven do not meet the guidelines provided by Fornell and Larcker (1981), including ATT (.466), PBC (.212), EV+ (.378), EV- (.368), and CBSI_E (.452). One construct, ATT_0, attained a borderline value of .494 and the remaining three constructs, i.e. the NBMC composites and CBSI_n, had values greater than .50.

The results of this investigation are somewhat inconsistent to the results found by Netemeyery et. al. (1991). In particular, the reliability of PBC in this investigation (.403) was much less than the value (.755) obtained by Netemeyer et. al. (1991) in their confirmatory analysis of the Theory of Reasoned Action and the Theory of Planned Behavior. Since these investigators did not include the antecedents of ATT, GSN, and PBC in their investigation, a comparison of these constructs' measurement is not possible.

In terms of other researchers' measurement of PBC, the reliabilities and inter-item correlations obtained with 2 to 5-item global measures ranged from .34 to .86 (See Tables 1-2, pp. 77-78). The reliability of all measures, with the exception of Netemeyer et. al. (1991), was calculated with coefficient alpha which assumes equal item reliability. Furthermore, results pertaining to the amount of variance captured by the construct were not provided. As previously discussed, a scale's reliability may appear adequate until the amount of variance captured by the construct is calculated. Therefore, the reliability coefficients included in Tables 1 and 2 that appear to represent adequate measurement of the PBC construct may, in fact, be misleading.
In summary, the measurement statistics presented in this section indicate that the indicators used in this investigation were less than adequate for several of the model's constructs. In particular, the measurement of physicians' perceived behavioral control and their belief-evaluations with respect to reporting a serious adverse drug event to the FDA was inadequate. The weakness of these constructs is traceable to highly unreliable indicators included in the construct's measure (See Table 13). Undoubtedly, this weakness affected the overall fit of the three models under study to the data.

Evaluation and Comparison of Nested Models

The estimation of parameters for the three models of interest included in this investigation allows the evaluation of the both the absolute and relative fit of the models to the study data. The null, uncorrelated factors, measurement, and saturated models were estimated in order to calculate three of the goodness-of-fit indices. This section presents and discusses results that empirically support the performance of each model under study, in terms of its structural parameter estimates and its overall ability to provide a plausible representation of the study data. This is followed by a comparison of inferential and descriptive measures of overall fit between the three models.

Evaluation and comparison of the TRA, TPB, and MTPB -2

Tables 15 through 17 present results helpful for evaluating the Theory of Reasoned Action, the Theory of Planned Behavior, and the Modified-2 Theory of Planned Behavior. Specifically, the structural parameter estimates that are directional are contained in Table 15. Table 16 provides the nondirectional
structural relationships, i.e. correlations, among the models' latent variables. The top portion of Table 17 presents the inferential and descriptive measures of overall goodness-of-fit that were obtained or calculated from the output created by LISREL during its estimation of the models.

The Theory of Reasoned Action. The estimation of the Theory of Reasoned Action (TRA) produced a chi-square of 2025.59 with 566 degrees of freedom. The hypothesis that the TRA is a plausible representation of this study's data was rejected (p = .000). Due to the strong tendency to reject the null hypothesis (i.e. the TRA holds exactly in the population), particularly with large samples, a significant chi-square was expected.

The descriptive goodness-of-fit measures supported the model's lack of fit to the study data. Specifically, although the RMSR was relatively low, all descriptive fit measures were substantially less than 1.0. As discussed in Chapter III, the TLI is less affected by sample size and is a good indicator of fit. The TLI for the Theory of Reasoned Action was .795, a value much lower than the desired value of .90 or greater. The RNFI (.866) calculated for the model was substantially higher than the other descriptive measures. Since this index reflects the fit of the model's structural component, independent of its measurement component, it is reasonable to suggest that the latter contributes to the model's lack of fit more than the former.

The results presented in Table 15 support most of the pathways included in the Theory of Reasoned Action. Specifically, physicians' attitudes toward reporting had a significant impact on their intentions to report to the FDA (p < .001). In turn, physicians' positive belief-evaluations were a significant predictor of their attitudes (p < .001). On the other hand, the negative belief-evaluations did not significantly
Table 15

NESTED MODEL COMPARISONS: STRUCTURAL PARAMETER ESTIMATES

(DIRECTIONAL)*

<table>
<thead>
<tr>
<th>Parameter</th>
<th>TRA</th>
<th>TPB</th>
<th>MTPB-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATT ---&gt; BI: $\beta_{12}$</td>
<td>.655d</td>
<td>.333d</td>
<td>.345d</td>
</tr>
<tr>
<td>EV(+) ---&gt; ATT: $\gamma_{21}$</td>
<td>.774d</td>
<td>.685d</td>
<td>.689d</td>
</tr>
<tr>
<td>EV(-) ---&gt; ATT: $\gamma_{22}$</td>
<td>.011a</td>
<td>-.014a</td>
<td>-.016a</td>
</tr>
<tr>
<td>GSN ---&gt; BI: $\beta_{13}$</td>
<td>.106c</td>
<td>.070b</td>
<td>.070b</td>
</tr>
<tr>
<td>NBMC$<em>A$ ---&gt; GSN: $\gamma</em>{33}$</td>
<td>.045a</td>
<td>.044a</td>
<td>.044a</td>
</tr>
<tr>
<td>NBMC$<em>{NA}$ ---&gt; GSN: $\gamma</em>{34}$</td>
<td>.596d</td>
<td>.597d</td>
<td>.597d</td>
</tr>
<tr>
<td>PBC ---&gt; BI: $\beta_{14}$</td>
<td>0</td>
<td>.503d</td>
<td>.509d</td>
</tr>
<tr>
<td>CBSI$<em>1$ ---&gt; PBC: $\gamma</em>{45}$</td>
<td>(.002a)**</td>
<td>.416d</td>
<td>.423d</td>
</tr>
<tr>
<td>CBSI$<em>e$ ---&gt; PBC: $\gamma</em>{46}$</td>
<td>(1.034d)</td>
<td>.718d</td>
<td>.713d</td>
</tr>
<tr>
<td>ATT$<em>O$ ---&gt; BI: $\gamma</em>{17}$</td>
<td>0</td>
<td>0</td>
<td>-.037a</td>
</tr>
</tbody>
</table>

* Values given for standardized variables

** Values in parentheses are not of particular interest in this model because the PBC ---> BI pathway is set at zero.

a - Not significant
b - p < .06
c - p < .01
d - p < .001
<table>
<thead>
<tr>
<th>Parameter</th>
<th>TRA</th>
<th>TPB</th>
<th>MTPB-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>EV(+) ---&gt; EV(-):  φ21</td>
<td>.356c</td>
<td>.351c</td>
<td>.351c</td>
</tr>
<tr>
<td>EV(+) ---&gt; NBMC_A:  φ31</td>
<td>.405c</td>
<td>.398c</td>
<td>.398c</td>
</tr>
<tr>
<td>EV(+) ---&gt; NBMCNA: φ41</td>
<td>.448c</td>
<td>.443c</td>
<td>.443c</td>
</tr>
<tr>
<td>EV(+) ---&gt; CBSI:  φ51</td>
<td>(.798c)</td>
<td>.760c</td>
<td>.760c</td>
</tr>
<tr>
<td>EV(+) ---&gt; CBSI_E: φ61</td>
<td>(.526c)</td>
<td>.479c</td>
<td>.480c</td>
</tr>
<tr>
<td>EV(+) ---&gt; ATT0:  φ71</td>
<td>(.520c)</td>
<td>(.527c)</td>
<td>.527c</td>
</tr>
<tr>
<td>EV(-) ---&gt; NBMC_A: φ32</td>
<td>.179c</td>
<td>.179c</td>
<td>.179c</td>
</tr>
<tr>
<td>EV(-) ---&gt; NBMCNA: φ42</td>
<td>.170c</td>
<td>.170c</td>
<td>.170c</td>
</tr>
<tr>
<td>EV(-) ---&gt; CBSI:  φ52</td>
<td>(.366c)</td>
<td>.358c</td>
<td>.358c</td>
</tr>
<tr>
<td>EV(-) ---&gt; CBSI_E: φ62</td>
<td>(.486c)</td>
<td>.472c</td>
<td>.472c</td>
</tr>
<tr>
<td>EV(-) ---&gt; ATT0:  φ72</td>
<td>(.170c)</td>
<td>(.169c)</td>
<td>.170c</td>
</tr>
<tr>
<td>NBMC_A ---&gt; NBMCNA: φ43</td>
<td>.665c</td>
<td>.666c</td>
<td>.666c</td>
</tr>
<tr>
<td>NBMC_A ---&gt; CBSI:  φ53</td>
<td>(.551c)</td>
<td>.498c</td>
<td>.498c</td>
</tr>
<tr>
<td>NBMC_A ---&gt; CBSI_E: φ63</td>
<td>(.341c)</td>
<td>.333c</td>
<td>.333c</td>
</tr>
<tr>
<td>NBMC_A ---&gt; ATT0:  φ73</td>
<td>(.125b)</td>
<td>(.125b)</td>
<td>.124b</td>
</tr>
<tr>
<td>NBMCNA ---&gt; CBSI:  φ54</td>
<td>(.503c)</td>
<td>.488c</td>
<td>.488c</td>
</tr>
<tr>
<td>NBMCNA ---&gt; CBSI_E: φ64</td>
<td>(.363c)</td>
<td>.352c</td>
<td>.352c</td>
</tr>
<tr>
<td>NBMCNA ---&gt; ATT0:  φ74</td>
<td>(.174c)</td>
<td>(.174c)</td>
<td>.173c</td>
</tr>
<tr>
<td>CBSI ---&gt; CBSI_E: φ65</td>
<td>(.646c)</td>
<td>.637c</td>
<td>.637c</td>
</tr>
<tr>
<td>CBSI ---&gt; ATT0:  φ75</td>
<td>(.296c)</td>
<td>(.285c)</td>
<td>.283c</td>
</tr>
<tr>
<td>CBSI_E ---&gt; ATT0: φ76</td>
<td>(.237c)</td>
<td>(.225c)</td>
<td>.233c</td>
</tr>
</tbody>
</table>

*Values given for standardized variables
** Values in parentheses are not of particular interest in the model because some directional pathways are set at zero.

a - p < 0.1
b - p < .05
c - p < .001
Table 17

NESTED MODELS: FIT COMPARISONS AND CHI-SQUARE DIFFERENCE TESTS

<table>
<thead>
<tr>
<th>Model</th>
<th>Chi-square</th>
<th>df</th>
<th>RMSR</th>
<th>GFI</th>
<th>TLI&lt;sup&gt;b&lt;/sup&gt;</th>
<th>PNFI(2)&lt;sup&gt;b&lt;/sup&gt;</th>
<th>RNFI(2)&lt;sup&gt;b&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Null</td>
<td>8538.66</td>
<td>630</td>
<td>.255</td>
<td>.293</td>
<td>----</td>
<td>----</td>
<td>----</td>
</tr>
<tr>
<td>Uncorrelated Factors</td>
<td>3624.96</td>
<td>595</td>
<td>.225</td>
<td>.608</td>
<td>.594</td>
<td>.584</td>
<td>----</td>
</tr>
<tr>
<td>TRA</td>
<td>2025.59</td>
<td>566</td>
<td>.094</td>
<td>.809</td>
<td>.795</td>
<td>.734</td>
<td>.866</td>
</tr>
<tr>
<td>TPB</td>
<td>1945.67</td>
<td>565</td>
<td>.088</td>
<td>.815</td>
<td>.805</td>
<td>.742</td>
<td>.909</td>
</tr>
<tr>
<td>MTPB-2</td>
<td>1944.98</td>
<td>564</td>
<td>.088</td>
<td>.815</td>
<td>.805</td>
<td>.740</td>
<td>.909</td>
</tr>
<tr>
<td>Measurement</td>
<td>1752.28</td>
<td>540</td>
<td>.085</td>
<td>.831</td>
<td>.821</td>
<td>.727</td>
<td>----</td>
</tr>
<tr>
<td>Saturated</td>
<td>0.00</td>
<td>0</td>
<td>.000</td>
<td>1.000</td>
<td>Div/0</td>
<td>.000</td>
<td>----</td>
</tr>
</tbody>
</table>

Differences in:

<table>
<thead>
<tr>
<th>Models</th>
<th>Chi-square</th>
<th>df</th>
<th>probability</th>
</tr>
</thead>
<tbody>
<tr>
<td>*TRA vs Null</td>
<td>6513.07</td>
<td>64</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>*TPB vs TRA</td>
<td>79.92</td>
<td>1</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>MTPB-2 vs TPB</td>
<td>- 0.69</td>
<td>1</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

* - Model fitting the sample data significantly better
a - Excluding the 'saturated' model, all chi-squares were significant (p = .000)
b - Equations for calculating TLI, PNFI(2), and RNFI(2) are found in Chapter III, pp. 251-252
impact their attitudes. Physicians' subjective norms were another significant predictor of their intentions to report or to not report (p < .01). Their perceptions of the social pressures to report or to not report were significantly influenced by 'nonauthoritative' (p < .001) but not by 'authoritative' referents. Lastly, all of the correlations between the model's exogenous latent variables were significant (p < .001).

The constructs within the Theory of Reasoned Action were able to account for 47% of the variance in physicians' intention to report a serious adverse drug event to the FDA. The amount of variance accounted for in attitude and subjective norms by their antecedents was 60.5% and 39.3%, respectively. While the model performs relatively well, as in previous applications, the amount of variance in behavioral intention that remains unexplained is substantial.

The Theory of Planned Behavior. The estimation of the Theory of Planned Behavior provided a chi-square of 1945.67 with 565 degrees of freedom. Similar to the TRA, the null hypothesis for this model, i.e. the Theory of Planned Behavior holds exactly in the population, was rejected (p = .000). Again, this finding was expected due to the hypothesis' tendency to be rejected when the model slightly deviates from the 'true' model, particularly with the study's large sample size.

The overall goodness-of-fit indices (See Table 17) for the model indicate that similar to the TRA, the Theory of Planned Behavior had shortcomings in fitting the study data. However, these shortcomings were slightly less than those observed with the TRA. Specifically, all descriptive measures of model fit, excluding RMSR, were higher for the Theory of Planned Behavior than the TRA. The increase in RNFI(2) is particularly important because this measure indicates the improvement in
fit due to the structural relationships of the Theory of Planned Behavior. That is, while the descriptive measures of fit indicate the improvement in fit seen with the TPB, the increase in RNFI(2) suggests that this improvement may be due to the addition of perceived behavioral control to the model's theoretical framework. In spite of this finding, however, the values of the other overall measures of fit are less than .90, indicating that the model's overall fit to the study data could be substantially better.

In terms of support for the directional pathways proposed in the Theory of Planned Behavior, Table 15 indicates that the structural parameter estimates that were significant in the TRA were also significant, for the most part, in the TPB. Specifically, attitude was a significant predictor of behavioral intention \((p < .001)\); \(EV(+)\) was a significant predictor of attitude toward the behavior \((p < .001)\); and 'nonauthoritative' referents were a significant predictor of subjective norms \((p < .001)\). Also, similar to the TRA, 'authoritative' referents and \(EV(-)\) did not significantly predict subjective norm and attitude, respectively. Although subjective norm was a significant predictor of intentions in the TRA \((p < .01)\), the significance of this path was lessened with the addition of perceived behavioral control \((p < .06)\).

Study results indicate that perceived behavioral control was a significant predictor of behavioral intentions for physicians' reporting behavior \((p < .001)\). In turn, both CBSI_1 and CBSI_E constructs significantly predicted perceived behavioral control \((p < .001)\). These results suggest that physicians' perception of control over reporting or not reporting to the FDA significantly influences their intention to report. Furthermore, this perception is determined by their beliefs about factors,
both internal and external to the physician, that influence their control to varying
degrees.

The correlation between the exogenous variables of the Theory of Planned
Behavior (see Table 16), i.e. nondirectional structural parameter estimates, were all
significant (p < .001). Relatively high correlations were found between EV(+) and
EV(-) (.760), 'authoritative' and 'nonauthoritative' NBMC (.666) and 'internal' and
'external' CBSI (.637). However, all of these correlations were significantly less
than 1.0 (p < .001), supporting the discriminant validity of the two-factor CBSI and
NBMC models found in the submodel analyses as well as the differentiation between
'behavioral beliefs' and 'control beliefs' as proposed by the TPB.

The constructs within the Theory of Planned Behavior accounted for 54.8% of
the variance in behavioral intention, a 7.8% increase by going from the TRA to the
TPB. In terms of the predictors of behavioral intention, the amount of variance
accounted for in ATT, GSN and PBC by their antecedents was 46.2%, 39.4%, and
1.0%, respectively. Compared to the TRA, the amount of explained variance in
ATT decreased whereas the amount in GSN remained constant.

The increase in explained variance in physicians' reporting intentions due to the
addition of the PBC--->BI pathway is substantially less than the increases obtained
in the confirmatory studies of students' voting behavior (25.7%) and weight loss
behavior (35.7%) conducted by Netemeyer et. al. (1991). As previously discussed
(see Table 5, p. 116), the increase in explained variance found by other investigators
have ranged from 5% to 45%. The amount of variance in behavioral intention not
accounted for in this analysis, however, is similar to findings by other researchers.
Specifically, the Theory of Planned Behavior was unable to explain approximately
45% of the variance in behavioral intention in this study. Previous investigations
have been unable to account for 31% to 84% of the variance in behavioral intentions (see Tables 3 and 4, pp. 102, 113). Therefore, it appears that the results discussed in this section are relatively consistent with other researchers' findings.

The modified Theory of Planned Behavior (MTPB-2). Estimation of the MTPB-2 generated an overall chi-square that was nearly equal to that obtained with the TPB. Specifically, a chi-square of 1944.98 (564 degrees of freedom) led to rejecting the null hypothesis, i.e. the MTPB-2 holds exactly in the population (p = .000). Again, the power of the chi-square statistic and the study's large sample size contributed, in part, to this finding.

The descriptive measures of the model's overall fit to the study data were nearly identical to the values of the goodness-of-fit measures generated or calculated for the TPB. For example, the RMSR, GFI, TLI, and RNFI(2) remained constant at .088, .815, .805, and .909, respectively. The minor decrease in the normed fit index, PNFI(2), may be attributable to the loss of one degree of freedom in going from the TPB to the MTPB-2, i.e. a loss in parsimony. However, this decrease may have been due to random chance. Interpretation of this model's fit indices are concordant with the interpretation of measures obtained for the Theory of Planned Behavior and thus, further discussion is not warranted at this time.

The directional and nondirectional structural parameter estimates of the MTPB-2 are also nearly identical to those estimated for the Theory of Planned Behavior. Again, attitude toward the behavior and perceived behavioral control were significant predictors of behavioral intention (p < .001) and subjective norm's prediction of intention was marginally significant (p < .06). The structural pathway added by the MTPB-2 (i.e. attitude toward the FDA ---> intention),
however, was not significant although the construct correlated significantly with the other exogenous variables (p < .05).

The constructs in the MTPB-2 explained 55.2% of the variance in behavioral intentions, an increase of 0.4%. Similar amounts of variance accounted for in the ATT, GSN, and PBC constructs were found between the TPB and the MTPB-2. Further discussion of these findings are provided in the following section.

**Inferential and Descriptive Comparisons of Fit**

The objective of this section is to identify the model proposed in this investigation that provided the most plausible representation of the study data. The previous section discussed two criteria needed to evaluate and compare the three models in an absolute sense, i.e. the models' goodness-of-fit and structural parameter estimates. These criteria are also applied in the inferential selection of the preferred model.

The three models of interest are nested and thus, the chi-square difference test was used to inferentially test the plausibility of one model over another. The bottom portion of Table 17 contains the results of the tests.

The inferential comparison of the TRA and the null model generated a significant difference in chi-square ($X^2 = 6513.07$, df = 64, p < .001). Therefore, the Theory of Reasoned Action was inferentially supported as a more plausible representation of the study data than the null model. The chi-square difference between the Theory of Planned Behavior and the TRA also showed a significant improvement in fit of the TPB over the TRA ($X^2 = 79.92$, df = 1, p < .001). Accordingly, the Theory of Planned Behavior was inferentially supported over the TRA as a more plausible representation of the study data. Finally, the
inferential comparison of the MTPB-2 and its nested TPB demonstrated no significance difference between the models. Therefore, the MTPB-2 was not supported as a more plausible representation of the study data.

The overall descriptive measures of fit that were discussed in the previous section support the inferential testing of the models. In short, all three models, i.e. TRA, TPB, and MTPB-2 did not fit the study data extremely well. However, the goodness-of-fit indices, in particular the RNFI(2), indicate that TPB provided the best fit and parsimony among the three models.

In terms of the models' structural parameters, ATT and GSN were significant predictors of BI in the Theory of Reasoned Action (p < .001 and p < .01, respectively). The Theory of Planned Behavior found that ATT and PBC were significant predictors of BI (p < .001). The addition of PBC to the model was accompanied with a marginally significant GSN --> BI parameter estimate (p < .06) and an increase in the amount of explained variance in behavioral intention. These results support the Theory of Planned Behavior as the model that providing the most plausible representation of the study data.

In summary, this investigation found that the Theory of Planned Behavior was the best representation of the study data among the three models of interest. The data analysis inferentially demonstrated that the TPB and MTPB-2 were superior to the TRA. The MTPB-2 provided no significant improvement of fit over the TPB and the former was less parsimonious than the latter. The findings from the inferential testing, the overall goodness-of-fit indexes, and the structural parameter estimates, then, supported the Theory of Planned Behavior as the model of choice in
this investigation for providing the most plausible representation of physicians' reporting intentions.

Results of Research Hypotheses

The previous section discussed the results of the nested model comparisons. This section uses these results to formally address the two remaining research hypotheses proposed in Chapter II. The hypotheses include:

H5.1: The Theory of Planned Behavior (TPB) will provide a significant improvement in fit to the data over the Theory of Reasoned Action (TRA).

H7.1: A modified model of the Theory of Planned Behavior in which physicians' attitude toward the FDA directly impacts their intention to report adverse drug events to the FDA (MTPB-2) will provide a significant improvement in fit to the data over the Theory of Planned Behavior (TPB).

In short, the previous section demonstrated that the Theory of Planned Behavior provided a significant improvement in fit to the study data than the Theory of Reasoned Action. Hence, Hypothesis 5.1 was supported in this investigation. However, this study failed to support a significant improvement in fit by the MTPB-2 as compared to the TPB. The Theory of Planned Behavior, then, was selected as

---

2 Due to the lack of strong support for the two-dimensional representation of EV in the submodel analyses, the TPB was also estimated with a unidimensional EV structure. A chi-square difference test supported the two-dimensional over the unidimensional representation ($\chi^2 = 121.19; df = 7; p < .001$).
the model preferred in this investigation to explain and predict physicians' spontaneous reporting intentions.

Results of the Specification Search

The Theory of Planned Behavior was used as the basis for the investigation's specification search. As previously discussed, the search is exploratory in nature, i.e. data driven. Thus, models resulting from respecified parameters could not be inferentially tested. However, the chi-square as well as other descriptive measures of overall fit were useful in evaluating the respecified models' fit to the study data. In addition, the single sample cross-validation index developed by Browne and Cudeck (1989) and discussed in Chapter III (see pp. 254-255) was useful in the model evaluation process.

The specification search consisted of two steps: (1) Step 1 in which an indicator of 'authoritative' NBMC was respecified as an indicator of 'nonauthoritative' NBMC, and (2) Step 2 in which an indicator of EV(-) was respecified as an indicator of EV(+). The two respecifications involved the measurement model of the Theory of Planned rather than its structural framework. The first two of the following three sections discuss the rationale for the respecifications and the results obtained with each step. The final section briefly addresses further respecification issues pertaining to this investigation.
Specification Search: Step 1

Previous sections have discussed the measurement and structural components of the Theory of Planned Behavior. In short, the data analysis provided evidence that the measurement model was weaker than the structural model. This finding was supported by the modification indices generated in estimating the Theory of Planned Behavior. As discussed in Chapter III, respecifications in the model would be based on both practical improvement of the model's fit as well as theoretical justification for the change.

The tables of modification indices (MI) and provided in the LISREL output were examined for large values relative to the model's overall chi-square of 1945.67. The largest value (176.068) was attained with the constraint of the FDA as an 'authoritative' normative referent. Although this indicator was a significant indicator of the 'authoritative' composite ($p < .001$), its respecification was justifiable in a practical sense due to the expected decrease in the overall chi-square.

In terms of theoretical justification, it seemed reasonable to believe that since physicians do not directly work with or for the FDA, they may not view the FDA as authoritative in nature. In addition, it was felt that many beliefs pertaining to the FDA, whether authoritative or not, was likely captured by the ATT construct.

The results of the first respecification are provided in Table 18. Since the first respecification involved the measurement component of TPB, the null model remained the same whereas the uncorrelated factors and measurement models differed. The decrease in chi-square obtained from respecifying the FDA as a 'nonauthoritative' referent was 205.37 with no loss in degrees of freedom. Although the results of this step can not be inferentially tested, the descriptive measures of fit support the respecification.
Table 18
SPECIFICATION SEARCH: COMPARISON OF PROPOSED MODELS

<table>
<thead>
<tr>
<th>Model</th>
<th>Chi-square</th>
<th>df</th>
<th>RMSR</th>
<th>TLI(^a)</th>
<th>PNFI(2)(^a)</th>
<th>RNFI(2)(^a)</th>
<th>(c_k^*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Null</td>
<td>8538.66</td>
<td>630</td>
<td>.255</td>
<td>----</td>
<td>----</td>
<td>----</td>
<td>----</td>
</tr>
<tr>
<td>TPB</td>
<td>1945.67</td>
<td>565</td>
<td>.088</td>
<td>.805</td>
<td>.742</td>
<td>.909</td>
<td>1946.13</td>
</tr>
<tr>
<td>STEP-1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncorrelated</td>
<td>3422.48</td>
<td>595</td>
<td>.222</td>
<td>.620</td>
<td>.608</td>
<td>----</td>
<td>----</td>
</tr>
<tr>
<td>Factors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step-1 Model</td>
<td>1740.30</td>
<td>565</td>
<td>.082</td>
<td>.834</td>
<td>.765</td>
<td>.907</td>
<td>1740.76</td>
</tr>
<tr>
<td>Measurement</td>
<td>1543.69</td>
<td>540</td>
<td>.079</td>
<td>.852</td>
<td>.750</td>
<td>----</td>
<td>----</td>
</tr>
<tr>
<td>STEP-2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncorrelated</td>
<td>3222.64</td>
<td>595</td>
<td>.220</td>
<td>.648</td>
<td>.632</td>
<td>----</td>
<td>----</td>
</tr>
<tr>
<td>Factors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Step-2 Model</td>
<td>1562.46</td>
<td>565</td>
<td>.066</td>
<td>.859</td>
<td>.785</td>
<td>.904</td>
<td>1562.92</td>
</tr>
<tr>
<td>Measurement</td>
<td>1361.44</td>
<td>540</td>
<td>.061</td>
<td>.879</td>
<td>.769</td>
<td>----</td>
<td>----</td>
</tr>
</tbody>
</table>

\(^a\) Equations for calculating TLI, PNFI(2) and RNFI(2) are found in Chapter III, pp. 251-253; equation for calculating \(c_k^*\) is found in Chapter III, p. 255.
As expected, the respecification had minimal impact on the RNFI(2) because no changes were made to the structural model. The other descriptive indices did improve, however, reflecting the measurement model's improvement in fit to the study data. Specifically, the RMSR decreased from .088 to .082, the TLI increased from .805 to .834, and the normed-fit index, PNFI(2) increased from .742 to .765. In addition, the single-sample cross-validation index was smaller (1740.76) for the model tested in Step 1 than the Theory of Planned Behavior (1946.13), signifying a preference of the former model over the latter.

These improvements were attained without a loss in the model's parsimony and a virtually absent modification index for the FDA as an indicator of 'authoritative' NBMC (MI = .293). In addition, the t-value supported the significance of the respecification (p < .001). Other indications of the improved measurement model are illustrated in Table 19. For example, the higher factor loading attained by this item (FDA) was accompanied by less error in the measure. In addition, both the composite reliability and the amount of variance extracted by the 'authoritative' and 'nonauthoritative NBMC composites increased substantially.

In sum, the first step of the specification search was a practical improvement in measuring the NBMC constructs. In addition, the respecification seems to have been a theoretically justified one.

Specification Search: Step 2

The second step of the specification search examined the output from the first step. Again, modification indices and t-values were evaluated to identify other possibly misspecified parameters in both the structural and measurement models. The highest MI was obtained with the constraint of error terms of two indicators for
Table 19
MEASUREMENT PROPERTIES OF RESPECIFIED INDICATORS AND THEIR CONSTRUCTS

<table>
<thead>
<tr>
<th>Model</th>
<th>Item</th>
<th>( \lambda_1 ) (factor loading)</th>
<th>Item Reliability</th>
<th>Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step-1</td>
<td>NM_1</td>
<td>.758</td>
<td>.575</td>
<td>.425</td>
</tr>
<tr>
<td></td>
<td>NM_2</td>
<td>.933</td>
<td>.870</td>
<td>.129</td>
</tr>
<tr>
<td></td>
<td>NM_3</td>
<td>.905</td>
<td>.819</td>
<td>.182</td>
</tr>
<tr>
<td></td>
<td>NM_4</td>
<td>.918</td>
<td>.843</td>
<td>.158</td>
</tr>
<tr>
<td></td>
<td>NM_5</td>
<td>.854</td>
<td>.728</td>
<td>.273</td>
</tr>
<tr>
<td></td>
<td>NM_6</td>
<td>.735</td>
<td>.540</td>
<td>.460</td>
</tr>
<tr>
<td></td>
<td>NM_7</td>
<td>.167</td>
<td>.028</td>
<td>.972</td>
</tr>
<tr>
<td>Step-2</td>
<td>BE_1</td>
<td>.680</td>
<td>.462</td>
<td>.538</td>
</tr>
<tr>
<td></td>
<td>BE_2</td>
<td>.468</td>
<td>.219</td>
<td>.781</td>
</tr>
<tr>
<td></td>
<td>BE_3</td>
<td>.630</td>
<td>.397</td>
<td>.603</td>
</tr>
<tr>
<td></td>
<td>BE_4</td>
<td>.677</td>
<td>.459</td>
<td>.541</td>
</tr>
<tr>
<td></td>
<td>BE_5</td>
<td>.667</td>
<td>.450</td>
<td>.555</td>
</tr>
<tr>
<td></td>
<td>BE_6</td>
<td>.734</td>
<td>.539</td>
<td>.461</td>
</tr>
<tr>
<td></td>
<td>BE_7</td>
<td>.927</td>
<td>.860</td>
<td>.140</td>
</tr>
<tr>
<td></td>
<td>BE_8</td>
<td>.185</td>
<td>.034</td>
<td>.966</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Construct</th>
<th>Number of indicators</th>
<th>Composite(^a) reliability</th>
<th>Variance(^a) extracted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step-1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NBMC(_a)</td>
<td>2</td>
<td>.916</td>
<td>.845</td>
</tr>
<tr>
<td>NBMC(_{NA})</td>
<td>5</td>
<td>.838</td>
<td>.543</td>
</tr>
<tr>
<td>Step-2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EV(+)</td>
<td>5</td>
<td>.764</td>
<td>.397</td>
</tr>
<tr>
<td>EV(-)</td>
<td>3</td>
<td>.685</td>
<td>.478</td>
</tr>
</tbody>
</table>

\(^a\) - Equations for calculating composite reliability and variance extracted are found in Chapter III, p. 230.
the direct measure of perceived behavioral control (MI = 63.578). The next highest index (MI = 147.001) was obtained with the constraint of an indicator used to measure EV(-) rather than EV(+). Specifically, physicians' belief-evaluation that their reporting to the FDA would encourage the agency to scrutinize the drug was viewed as a positive rather than a negative consequence.

In terms of practical significance, the respecification of either parameter was expected to substantially decrease chi-square although the correlation of the error terms would decrease the statistic more. The decision between these two, however, was based on the theoretical justification of freeing one parameter rather than the other.

Some have addressed the uncritical use allowing measurement errors to correlate in covariance structural modeling. Gerbing and Anderson (1984, p. 572) note that "adding correlated measurement errors to structural equation models will nearly always improve fit; the important question is whether their addition improves the substantive interpretation of the model".

In terms of this step of the specification search, the correlation of the two error terms was not obviously theoretically justified. Although the respecification of this parameter would have provided the model with the most improvement in fit to the study data, it would not have contributed to the model's theoretical meaningfulness.

The respecification of the other parameter, however, was theoretically justified. Although the pilot study had suggested that "encouraging the FDA to scrutinize the drug" might result in the FDA removing a good drug from the market, it is reasonable to believe that physicians may have felt that "encouraging the FDA to scrutinize the drug" might result in the FDA removing a dangerous drug from the market. Thus, this belief-evaluation statement may have been viewed positively
along with the other positively-viewed belief-evaluations (e.g. "would help prevent dangerous side effects", "would discourage the use of borderline or high-risk drugs").

Step-2 of the specification search, then, involved specifying the above belief-evaluation statement (BE5) as an indicator of EV(+) rather than EV(-). Again, the null model remained the same but the parameter respecification changed the measurement and the uncorrelated factors model. Similar to the first step of the specification search, the resultant model's chi-square decrease from 1740.30 to 1562.42, a chi-square difference of 177.84 with no loss in degrees of freedom. Although the difference between the models resulting from the specification search's first and second steps can not be inferentially tested, the results of this respecification appear favorable.

The overall goodness-of-fit indexes support the decrease in chi-square. Specifically, the RMSR decreased from .082 to .066; the TLI index increased from .834 to .859; and the index reflecting any loss of parsimony, i.e. PNFI(2), increased from .765 to .785. Again, since the RNFI(2) reflects the goodness-of-fit of the model's structural framework independent of its measurement component, its value remained relatively constant because the parameter respecification involved only the measurement model. The improvement in the measurement model is further supported in Table 19. The respecification of BE item increased both the composite reliabilities of and the amount of variance extracted by EV(+) and EV(-).

Results of the second step of the specification search, then, suggest that the modification made to the measurement model improved the overall fit of the Theory of Planned Behavior to the this investigation's data. This suggestion is further supported by the single-sample cross-validation index calculated for this model.
Specifically, the value calculated for the model resulting from step 2 of the search was 1562.92, a value much lower than that found for the Step-2 model (1740.76).

**Further Respecification Considerations**

Upon completing the second step of the specification search, the LISREL output from this step was examined for further misspecified parameters. The modification indices indicated that further respecification might improve the fit of both the measurement and structural components of the model. In addition, T-values were examined to determine if constraining some parameters to equal zero would increase the model's parsimony without sacrificing the model's overall fit to the study data. However, two steps had been undertaken in the specification search and further respecification needed to be evaluated, in terms of its practical and theoretical contribution to this investigation's model.

The modification indices indicated that many parameters had high values (e.g. greater 20) and thus, misspecification extended throughout the model. Although the number of respecified parameters could be endless, only the modifications indices that had extremely high values relative to the overall chi-square were of primary interest in this investigation. The model resulting from the second step of the specification search had a chi-square value of 1562.46. Three indices remained from the search's second step with values greater than 100.

A decrease in the overall chi-square by 100 or more represented a practical improvement to the model. However, the second criteria for deciding to relax a constrained parameter, i.e. theoretical justification, warranted attention.

The highest modification value, 163.626, was, again, the correlation between the two error terms in the direct PBC measure that was constrained to equal zero. The
lack of theoretical justification for freeing this parameter was adequately addressed in the previous section.

The MI of two other parameters was greater than 100: the CBSI\textsubscript{I} --\(\rightarrow\) BI pathway (MI = 118.604) and the CBSI\textsubscript{E} --\(\rightarrow\) BI pathway (MI = 117.737). According to the theoretical development of the perceived behavioral control construct and its antecedents proposed in this investigation, the effects of both the internal and external CBSI composite on behavioral intention are mediated by PBC. Although the composites are significant predictors of PBC in this investigation (p < .001), the results of this analysis suggest that they may have a direct effect on behavioral intention as well as their indirect effect.

An alternative explanation for the high modification indices is the inadequate measurement of the perceived behavioral control construct, as discussed in a previous section. The weakness in this measure, as well as the theoretical structure of the PBC construct that was developed in this investigation provided little theoretical justification for adding one or both of these structural pathways to the Theory of Planned Behavior. Furthermore, there was no justification for the existence of one pathway versus the other. Therefore, neither parameter was relaxed as a third step of the specification search.

Since further improvements in fit were expected only if theoretically unjustified structural pathways were respecified or if several respecifications were made in the measurement model, the effort to improve the model's overall fit to the data was ceased in order to decrease the risk of capitalizing on chance characteristics of the study data. Subsequently, efforts turned toward examining the parsimony of the model resulting from Steps 1 and 2 of the specification search.
As previously discussed, the measurement properties of the many of observed variables and the constructs they purportedly measured were lacking in construct validity. Steps 1 and 2 of the specification search demonstrated, in part, the potential gain in the measurement model's fit if indicators were respecified or dropped as measures. However, continued respecification of the measurement model would capitalize on the chance characteristics of the study sample and was not theoretically useful or practical in this investigation.

Lastly, T-values were examined to evaluate the significance of structural pathways in the model resulting from the specification search's second step. Similar to that found with the estimation of the Theory of Planned Behavior, all directional pathways were significant at alpha equal to .001 except the GSN-->BI pathway (p < .06), and the EV(-)-->ATT and 'authoritative' NBMC-->GSN pathways which were not significant. However, all proposed pathways were retained in the model, following the usual standard of practice with the model.

In sum, further steps in the specification search were not undertaken in this investigation. The search provided some improvement in fit of the model to the data, specifically for the measurement component of the Theory of Planned Behavior. Although further improvements in fit or parsimony could have been attained, the practical and theoretical gain from such actions did not seem to justify the risk of capitalizing on the chance characteristics of the study data.
Summary of Model Results

The data presented in this chapter addressed three primary aspects of this investigation's examination of the Theory of Planned Behavior. These include: (1) analysis of the submodels developed in Chapter II, and (2) estimation and evaluation of the Theory of Planned Behavior as a model of physicians' reporting intentions in both absolute and relative perspectives, and (3) examination of additions to or respecifications of the Theory of Planned Behavior that might increase the amount of variance explained in physicians' reporting intentions.

The analysis of the submodels supported a two-dimensional structure underlying both expectancy-value attitude and the normative belief-motivation to comply composite. Similar to the findings of Bumkrant and Page (1988), the two-factor EV composite was comprised of positive belief-evaluations and negative belief-evaluations with respect to physicians' reporting behavior. The two-factor normative model consisted of one factor representing referents that might be perceived to be in 'authoritative' positions, i.e. having the power to establish and enforce standards of medical practice, policies, or procedures. The second factor represented referents that did not have authority or power over a physicians' practice; rather these referents were colleagues or peers that socialized or interacted with the physician either individually or as a group.

The analysis of the perceived behavioral control submodel supported the CBSI composite proposed in this investigation as the antecedent of perceived behavioral control rather than the set of control beliefs proposed by Ajzen and his colleagues. Furthermore, the two-factor representation of this composite was supported over the one-factor model.
This investigation supported the Theory of Planned Behavior as the model of choice for explaining and predicting physicians' spontaneous reporting intentions. Perceived behavioral control was found to be a significant predictor of intentions, as well as attitude toward the behavior. Comparison of this study's results with others' findings is difficult in that: (1) all but Ajzen and Madden (1986) have incorporated a belief-based measure of perceived behavioral control, and (2) all but Netemeyer et. al. (1991) have used hierarchical regression rather than confirmatory methods.

The analysis of the measurement and structural components of the TPB indicated that the model was lacking in its fit to the study data. The overall goodness-of-fit indices suggest that this lack of fit may be more attributable to the measurement rather than the structural component of the model. The specification search supported these findings in that modification indices were high for measurement model parameters. The overall model of physicians' reporting intentions resulting from the analysis of this investigation's research hypotheses (i.e. prior to the specification search) is illustrated in Figure 16.
Figure 16: Overall Structural and Measurement Model with Standardized Parameter Estimates: Resultant Model
CHAPTER V
CONCLUSIONS AND RECOMMENDATIONS

The objective of this final chapter is three-fold. First, results of this investigation's data analysis are summarized with respect to their relevance to physicians' spontaneous reporting of adverse drug events. Second, conclusions drawn from the investigation's results as well as their relevance to previous research findings are discussed. Third, limitations on the interpretation of the study's results and their generalizability are offered. Finally, this chapter addresses recommendations for future investigations.

Summary: Spontaneous Reporting Intentions

This investigation examined an increasingly important concern in today's financially expanding health care system: physicians' reporting of serious adverse drug events to the FDA. Research suggests that with the expected growth in our aged population who are more prone to adverse drug events, the use of national health care resources will continue to increase. Physicians' reporting of adverse drug events positively impacts health care utilization by identifying drugs with serious adverse effects. Early identification of serious adverse drug events can result in stricter labeling of the marketed product or the drug's removal from the market, thus decreasing the future occurrence of morbidity and mortality. Although the
rationale behind and process of identifying adverse drug events seem relatively simple, the lack of reporting in this country is undeniably significant and reasons underlying physicians' decision to report or to not report adverse drug events are minimally known.

This study addressed the issue of physicians' spontaneous reporting behavior within a theoretical framework. This framework was based and built upon the Theory of Planned Behavior. The development and testing of this model furthered the conceptual understanding of the perceived behavioral control construct and the validity of the model's constructs. In this process, a greater understanding was gained with respect to the factors underlying physicians' attitudes about reporting, the individuals or groups they perceived to have expectations about their reporting behavior, and their perception of control over the successful performance of reporting to the FDA.

In terms of explaining or predicting physicians' intentions to report a serious adverse drug event to the FDA, significant predictors included their attitude toward reporting and their perceived control over the reporting process ($p < .001$). Physicians' perception of the social pressures placed on to report to not report was marginally significant.

Beliefs about the positive consequences of reporting a serious adverse drug event significantly influenced physicians' attitudes toward reporting ($p < .001$). While beliefs about the negative consequences of reporting had a negative effect on their attitudes, this effect was not significant.

Although physicians' perceptions of the social pressures placed on them to report or to not report was marginally significant, this perception was significantly determined by colleagues, medical organizations, and other peer-oriented individuals
or groups. Agencies or groups with regulatory power were not significant social
influencers.

As noted, physicians' perception of their control over spontaneously reporting
was a significant predictor of their intention to report. Factors internal to physicians
that significantly influenced this perception included their feelings of obligation to
report, their ability or knowledge about reporting, their general sense of motivation,
and time. In terms of factors external to physicians, the accessibility of the
necessary reporting forms, assistance in reporting, and time constraints significantly
influenced their perception of control over the behavior.

Conclusions

This section attempts to integrate the investigation's major findings and to
discuss them as they relate to existing literature in both the marketing and
pharmaceutical literatures. As one approach toward this endeavor, the goals of this
study are addressed, in terms of both the theoretical and pragmatic implications, or
significance, of its results. The theoretical implications pertain primarily to the
Theory of Planned Behavior and its conceptual development. Physicians'
participation in spontaneous reporting of adverse drug events constitute the majority
of pragmatic implications.

The Theory of Planned Behavior was selected as the framework for developing a
model of physicians' spontaneous reporting behaviors because previous research
indicated that physicians may perceive some lack of control over reporting to the
FDA, thus suggesting the appropriateness in using the Theory of Planned Behavior.
As discussed in Chapter II, the TPB has received mixed support by previous
researchers. This study proposed that several questions, or issues, pertaining to the model may have contributed to this mixed support. These issues included: (1) the structure, or underlying dimensional nature, of both expectancy-value attitude and the normative belief-motivation to comply composite as components in the TPB, (2) the antecedent of perceived behavioral control, (3) the structure, or underlying dimensional nature, of this antecedent, (4) the adequacy of the TPB in predicting physicians' reporting intentions in a relative sense, i.e. as compared to the Theory of Reasoned Action, (5) the sufficiency of the TPB in an absolute sense, i.e. in terms of other variables significantly improving the fit of the TPB to the data collected in this investigation, and (6) the role of past behavior in the TPB and any potential overlap of it with perceived behavioral control.

Chapter II addressed the issue of determining the dimensionality of constructs included in any model, including the TRA and the TPB, before developing and using an instrument that is designed for unidimensional measurement. This is not a novel concern in that previous studies have supported multidimensional representations of both expectancy-value attitude and the normative belief-motivation to comply composite. Dimensionality is not an issue of construct validity, however, according to Ajzen and his colleagues because the two behavioral intention models are derived from expectancy-value theory which assumes that attitude is a function of all salient beliefs. Since this investigation found support for multidimensional representations of both the NBMC and CBSI composites, the persistence of an assumption that not only lacks support, but is empirically refuted, questions the wisdom of researchers avoiding or discounting this issue in their tests of the TRA and TPB.
The antecedent of perceived behavioral control was an issue of high priority in this investigation. Chapter II proposed that the mixed support for the Theory of Planned Behavior obtained in empirical studies may be attributed, in part, to the level of conceptualizing perceived behavioral control in those investigations. This study's support of the antecedent as a composite, specifically control belief-strength of influence, rather than as a set of beliefs about the likelihood or frequency of 'control factors' occurrence suggests that prior attempts to conceptualize this construct have been inadequate. Inadequacies in the construct's conceptualization have overlapped with inadequacies in operationalizing the concept, likely resulting in its mixed support in empirical studies. This investigation, supports a more intricate conceptualization of perceived behavioral control than previously published attempts. This support is concordant with Ajzen's (1991) newest direction in conceptualizing the construct as described in Chapter II.

Since the results indicated that physicians' perception of control over reporting had a significant effect on their intentions to report, the selection of the theory as a basis of study was supported in this investigation. These results suggest that physicians' spontaneous reporting of adverse drug events is involitional to some extent, influenced by both internal and external factors that affect their control over the behavior. Based on the results of this investigation, the conclusion that the Theory of Reasoned Action provides a less sufficient model for explaining and predicting physicians' spontaneous reporting intentions is an appropriate and justifiable one. These results support previous research finding that the Theory of Planned Behavior is a more sufficient model than the Theory of Reason. As noted in Chapter II, determining whether or not the gain in sufficiency counterbalances the loss in model parsimony is a difficult task. The parsimony-adjusted goodness-of-fit
indexes presented in Chapter IV, however, demonstrates that the gain in the TPB's sufficiency is greater than its loss in parsimony.

In terms of the sufficiency, i.e. adequacy, of the Theory of Planned Behavior, this investigation examined whether or not physicians' attitudes toward the FDA, an object, would increase the amount of variance explained in physicians' reporting intentions. This study failed to support this variable as a significant predictor of intentions. However, the amount of unexplained variance in physicians' reporting intentions suggest that components outside the model may add to the sufficiency of the Theory of Planned Behavior.

The last issue that specifically addresses the theoretical implications of this investigation's results involves the role of past behavior in the Theory of Planned Behavior and its potential overlap with perceived behavioral control was not resolved in this study. Unfortunately, no conclusions can be offered on this issue due to the infrequency of physicians' past reporting behavior.

In terms of conclusions pertaining to the pragmatic significance of this study's results, this study supported previous findings of physicians' under-reporting to the FDA. Specifically, the national sample surveyed by Rogers et. al. (1988) found a 5% rate of reporting adverse drug events to the FDA whereas this investigation's rate was 8%. Although physicians in both samples were voluntary participants and the response rates were relatively low, the results combined from both studies lend support to the extent of under-reporting in the United States that has been found by Griffin (1986).

This investigation's results also suggest that the factors underlying physicians' decision to report or not report may consist of a intricate network of beliefs, i.e. beliefs about the behavior of reporting, beliefs about others who have expectations
regarding physicians' reporting behavior, and beliefs about physicians' control over their reporting. Some of the sets of beliefs have more impact on physicians' intention to report than others. For example, this study's results suggest that physicians' beliefs about both the act of reporting a serious adverse drug event to the FDA and their control over reporting significantly impact their intention to report or to not report. However, beliefs about the expectations of others, particularly those that are not colleagues, appear to have a non-significant influence on their decision, or intent, to report. This finding seems logical in that physicians are often viewed as authoritative individuals who "run their own professional practices" rather than assume a submissive or approval-seeking role from others.

Limitations and Generalizability of the Study

The interpretation of this investigation's results is restricted by several limitations. These limitations can be classified into one of two categories: (1) limitations in the theoretical model used and further developed to explain physicians' reporting behaviors and (2) limitations in the research design and procedure. These limitations are first addressed followed by a discussion on the generalizability of the study's results.

Limitations involving the theoretical model used and further developed to explain physicians' reporting that may limit the interpretation of this investigation's results include assuming that physicians' reporting behavior was explainable and predictable with a multi-attribute model. Previous research on a useful theoretical framework for the study of physicians' reporting behavior or any other health professional's reporting behavior was nonexistent. Although numerous theoretical models
developed to explain and predict human behavior were available in the literature, this investigation assumed that a behavioral intention model was a valid and useful model on which to base a model of physicians' reporting behavior. The selection of this particular group of models for developing the model in this investigation may have limited the results to the extent it directed or forced physicians to respond to measures and provide data that inaccurately represented the factors underlying physicians' spontaneous reporting behavior.

The major source of limitations on interpreting this investigation's results involves the study's research design and procedure. First and foremost, the method in which the data was collected is a major limitation. Although the national sample was purportedly a randomly selected group, the selection process was conducted by an outside research firm and thus, not completely verifiable. In addition, the local sample was not randomly selected; rather, a census was used. Therefore, this study's overall sample was similar to a convenience sample and can not be assumed as a representative sample of the physician population.

A second limitation in collecting the data involves the voluntary participation in the main study and the low response rate encountered. The use of voluntary participation further decreased the likelihood of an adequate representation of the target population. Although the investigation could not mandate subjects' participation, the limitation in interpreting the results obtained from the data analyses must be acknowledged. Specifically, the lack of participation by the majority of physicians may have biased the results if the behavior of 'not participating in the study' was reflective of 'not participating in reporting adverse drug events'. The comparison of early versus late responders was an attempt to assess the potential nonresponse bias. Furthermore, the primary objective of this
investigation involved examining and comparing the models proposed to explain reporting behavior rather than attaining exact measures of physicians' attitudes, beliefs, intentions, etc.

Another limitation in collecting the data involved the development and administration of the measurement instrument. Development of the data collection instrument was based on results of the elicitation exercises conducted during the exploratory study. The initial attempt to conduct the exploratory research via mail survey encountered an extremely poor response rate. This problem necessitated changing both the estimated number of participants in the exploratory research and the procedure by which the study was conducted. These modifications in the exploratory study's design may have identified salient beliefs, normative referents, etc. less effectively or efficiently than originally anticipated. The use of the literature to further identify and validate salient behavioral, normative, and control beliefs was an attempt to curtail the limitations introduced by the exploratory study.

The elicitation exercises introduced another potential limitation in this investigation. Specifically, although the techniques for eliciting salient belief-evaluation statements and normative referents have been substantially addressed in the literature, the technique for eliciting 'control factors' have been minimally discussed. In addition, the categorization of these factors ('internal' and 'external' factors used in this investigation) have received little attention. Consistent with the elicitation of salient belief-evaluations and normative referents, the elicitation of salient 'control factors' in this investigation was accompanied by comprehensible definitions and examples where appropriate. Therefore, the interpretation of this study's results may be limited to the extent that the technique confused or 'led' study participants in providing their responses.
The data analysis introduces other potential limitations to the interpretation of this study's results. First, the use of multiplied products as indicators in the measurement and structural components of the proposed overall reporting models has unknown implications for the results. Some of the issues are: (1) whether or not the two measures that are normally distributed independently are normally distributed when they are multiplied and (2) the meaning of multiplied error terms. This investigation recognized the potential problem associated with the issues outlined above and attempted to address them in several ways. First, previous literature suggested that the use of multiplied products in LISREL analyses does not always pose the problems claimed by some researchers. Second, the issue of multivariate normality was examined and the extent of skewness and kurtosis found in the final set of multiplied indicators was relatively minor. Third, the primary purpose of the study involved comparisons between various representations of model components and between various models, for the most part, nested within the same covariance matrix. Therefore, any unwanted effects generated by multiplied error terms or product indicators would be constant between comparisons and should not interfere with their results.

One exception to the reasoning offered above was the comparison of the CBSI and CB submodels. Specifically, the indicators of the construct 'CBSI' were products whereas the indicators of the 'CB' construct were not products. Although these submodels were not inferentially compared, the CBSI submodel was selected for inclusion in the overall reporting model because of its superior goodness-of-fit indices. The decision to select the CBSI submodel limits the interpretation of this study's results in that the difference found between the models may be due to: (1) real differences between the models' ability to predict perceived behavioral control,
(2) differences between measurement properties of the indicators, or (3) a mixture of 'real' and 'measurement' differences.

A significant limitation to the interpretation of this study's results pertain to the inadequate belief-based measure of attitude toward the behavior and inadequate global measure of perceived behavioral control. As a result of these measures' unreliability, a more accurate picture of the structural relationships among the models' constructs was limited. The high modifications indices for the CBSI→BI pathways likely reflect the inadequacy of the measurement model used in this study.

The generalizability of this study's results has been addressed in Chapter I. Briefly put, this research only examined physicians' intention to report serious adverse drug events to the FDA. Therefore, it is inappropriate to generalize its results to: (1) health care providers other than physicians, (2) physicians who belong to other categories (i.e. D.O., M.D) or target populations, (3) adverse drug events that are not serious, or (4) physicians' reporting of serious adverse drug events to parties other than the FDA.

Recommendations for Future Research Endeavors

Both the difficulties encountered in this investigation and its results suggest several areas for future research endeavors. These areas can be categorized into two classes: (1) research pertaining to the Theory of Planned Behavior and (2) research pertaining to spontaneous reporting of adverse drug events.

Many questions remain to be answered about the Theory of Planned Behavior. First and foremost, further research is needed to address the conceptualization of perceived behavioral control and its role in the TPB. Study of the antecedent of the
PBC construct and its underlying dimensionality may provide further support for this investigation's results. In addition, further research is needed in developing a valid and reliable direct measure of perceived behavioral control. This accomplishment could help determine if the CBSI antecedents directly impact behavioral intention or if the results obtained in this study were based primarily on the poor measure of PBC.

The results of this investigation also suggest that further attention is warranted in comparing and validating the differences between behavioral and control beliefs. Specifically, the initial results of the exploratory study's elicitation exercises suggested that some beliefs were perceived as behaviorally-oriented as well as behaviorally-oriented. Careful study is needed to validate the CBSI and EV constructs.

Lastly, study is needed to further advance the knowledge of unidimensional versus multidimensional measures. Theories relying on the 'expectancy-value' proposition of incorporating all salient beliefs into one measure should be reexamined.

Areas of future research with respect to spontaneous reporting behaviors include: (1) the spontaneous reporting of serious adverse drug events by health care professionals other than physicians, (2) the reporting of adverse drug events of varying severity, (3) the reporting of serious adverse drug events to parties other than the FDA, and probably most importantly, (4) methods or interventions to improve physicians, as well as other health care professional, reporting of serious adverse drug events.
APPENDIX A
EXPLORATORY STUDY: DATA COLLECTION INSTRUMENT
Dear Doctor:

We request your participation in a doctoral research project which is being conducted at the Ohio State University. This project investigates an increasingly important issue within today's health care industry: the surveillance of adverse drug events (ADEs) or reactions. Physicians encounter ADEs in all aspects of their clinical practice. With estimates that ADEs occur in 3 to 28% of hospitalized patients, it is obvious why this issue is of interest to researchers, health care providers, pharmaceutical manufacturers, and governmental/nongovernmental agencies.

The following survey is brief, requiring approximately 10 minutes of your time. Please be assured that your responses will be kept confidential. Your honest and complete responses will enable us to develop a data collection instrument for our project's second phase which will thoroughly examine physicians' ADE reporting behaviors. A separate group of physicians will participate in this phase and thus, you will not need to be recontacted.

Your participation in Phase I of our research project would be greatly appreciated. We request that you complete and return your questionnaire in the postage-paid, self-addressed envelope by Thursday, May 16, 1991. The results from the completed project will be gladly provided upon your request. Thank you for your consideration.

Paula A. Funk, M.S., R.Ph.
Chairman & Dow Professor
Pharmaceutical Administration
The Ohio State University

Robert E. Burnkrant, Ph.D.
Associate Professor
Marketing
The Ohio State University

Dev S. Pathak, D.B.A.
Pharmaceutical Administration
The Ohio State University

John J. Kennedy, Ph.D.
Professor
Education Services and Research
The Ohio State University
INSTRUCTIONS

The Food and Drug Administration (FDA) defines an adverse drug event (ADE) or reaction as "any adverse event associated with the use of a drug in humans, whether or not considered drug related" (21 CFR 310.301 (b)). This definition includes an ADE which: (1) occurs during drug use in professional practice, (2) occurs from either intentional or accidental overdose, (3) occurs from drug withdrawal, or (4) is a significant failure of expected pharmacological effect. ADEs have a wide range of manifestations. Some are minor (e.g. nausea, headache, drowsiness), require little or no treatment, and may even remain undetected. Others are serious (e.g. anaphylaxis, aplastic anemia, arrhythmia) and may result in drug therapy, hospitalization or its prolongation, and even death. ADEs may also be classified as "labeled" (i.e. expected) or "unlabeled" (i.e. unexpected). An unexpected or unlabeled ADE is one that is not listed in the current labeling for the drug product (i.e. package insert). Although unlabeled ADEs may attract the most interest, the definition of an ADE also includes labeled ones.

When an ADE occurs in a patient, the practitioner has several options for reporting it if he or she so desires. Reports may be filed with: the manufacturer, a hospital's drug surveillance program, the FDA, a pharmaceutical representative, a specialized registry (e.g. U.S.P.), etc. The physician may also decide to submit an anecdotal report or an article to the professional literature.

This study pertains specifically to physicians' reporting of ADEs directly to the FDA. While this process may be initiated with a telephone call to the FDA, this investigation addresses physicians' use of the FDA's Spontaneous Reporting System (SRS). The SRS program consists of physicians' written completion of FDA's preprinted reporting forms (FDA Form 1639).

As you read and answer the first 5 questions, please consider each one in terms of your participation in the FDA's written SRS program. Your complete and precise responses will be greatly appreciated.

1. Please list at least 3 ADVANTAGES of your spontaneously reporting ADEs directly to the FDA. An advantage is a favorable gain or benefit associated with a given behavior. For example, one advantage of voluntarily participating on a hospital's Pharmacy and Therapeutics (P & T) committee may be your greater impact on formulary drug selection.

(1)______________________________________________________________
(2)__________________________________________________________________________
(3)__________________________________________________________________________
2. Please list at least 3 DISADVANTAGES of your spontaneously reporting ADEs directly to the FDA. A disadvantage is an unfavorable or negative consequence of a given behavior. In the example provided above, a disadvantage may be that the committee meetings are boring or uninteresting.

(1) _____________________________________________________________

(2) ____________________________________________________________________________

(3) ____________________________________________________________________________

3. Please list at least 3 groups or individuals who may have expectations about whether or not you should report ADEs directly to the FDA. For the example of your participation on a hospital’s P & T committee, your colleagues, the AMA or other professional associations, spouse, friends, etc. may approve or disapprove of your committee service.

(1) _____________________________________________________________

(2) ____________________________________________________________________________

(3) ____________________________________________________________________________

4. Several factors may IMPED your control over spontaneously reporting ADEs to the FDA. These factors may be internal or external to you. Internal factors are individual characteristics and may include your skills, level of information, motivation, emotions, sense of personal control, etc. On the other hand, external factors are characteristic of the situation, such as time, opportunity, availability of specific items necessary for your control, etc. Please list at least 3 INTERNAL and 3 EXTERNAL factors which may PREVENT or IMPAIR your reporting ADEs via FDA’s 1639 form.

<table>
<thead>
<tr>
<th>INTERNAL FACTORS</th>
<th>EXTERNAL FACTORS</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) ______________</td>
<td>(1) ______________</td>
</tr>
<tr>
<td>(2) ______________</td>
<td>(2) ______________</td>
</tr>
<tr>
<td>(3) ______________</td>
<td>(3) ______________</td>
</tr>
</tbody>
</table>
5. Both internal and external factors may IMPROVE your control over spontaneously reporting ADEs directly to the FDA. Using the definitions of internal and external factors provided in the previous question, please list at least 3 INTERNAL and 3 EXTERNAL factors which might FACILITATE or IMPROVE your reporting ADEs via FDA's 1639 form.

**INTERNAL FACTORS**

(1) ____________________________  
(2) ____________________________  
(3) ____________________________

**EXTERNAL FACTORS**

(1) ____________________________  
(2) ____________________________  
(3) ____________________________

6. Before today, were you aware that the FDA maintains a spontaneous reporting system (SRS) in which physicians submit written documentation of ADEs encountered in their clinical practice? (Please check response)

____ YES  ____ NO  ____ NOT SURE

7. What is the likelihood that you would accurately remember the NUMBER of ADEs encountered in your clinical practice within the following time periods? (Please circle number for each time interval)

<table>
<thead>
<tr>
<th></th>
<th>VERY UNLIKELY</th>
<th>VERY LIKELY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within the past MONTH</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
</tr>
<tr>
<td>Within the past 3 MONTHS</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
</tr>
<tr>
<td>Within the past 6 MONTHS</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
</tr>
<tr>
<td>Within the past 1 YEAR</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
</tr>
<tr>
<td>Within the past 2 YEARS</td>
<td>1  2  3  4  5  6  7</td>
<td></td>
</tr>
</tbody>
</table>
8. What is the likelihood that you would accurately remember the LAST ADE encountered in your clinical practice for the following time periods? (Please circle number for each time interval)

<table>
<thead>
<tr>
<th>Time Period</th>
<th>Very Unlikely</th>
<th>Very Likely</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within the past 1 WEEK</td>
<td>1  2  3  4  5</td>
<td>6  7</td>
</tr>
<tr>
<td>Within the past 1 WEEK</td>
<td>1  2  3  4  5</td>
<td>6  7</td>
</tr>
<tr>
<td>Within the past 1 MONTH</td>
<td>1  2  3  4  5</td>
<td>6  7</td>
</tr>
<tr>
<td>Within the past 3 MONTHS</td>
<td>1  2  3  4  5</td>
<td>6  7</td>
</tr>
<tr>
<td>Within the past 6 MONTHS</td>
<td>1  2  3  4  5</td>
<td>6  7</td>
</tr>
<tr>
<td>Within the past 1 YEAR</td>
<td>1  2  3  4  5</td>
<td>6  7</td>
</tr>
<tr>
<td>Within the past 2 YEARS</td>
<td>1  2  3  4  5</td>
<td>6  7</td>
</tr>
</tbody>
</table>

Thank you for completing this survey. Please return in enclosed postage-paid, self-addressed envelope by Thursday, May 16, 1991.
APPENDIX B

PRIMARY INVESTIGATION: DATA COLLECTION INSTRUMENT
Dear Doctor:

We request your participation in a research project which is being conducted at The Ohio State University. This project investigates an increasingly important issue within today's health-care industry: the surveillance of adverse drug events (ADEs). ADEs impact morbidity, influencing hospital admission and often increasing the length of hospital stay. In some cases, ADEs precipitate death.

The enclosed survey has been developed from data obtained from physicians participating in this project's first phase. The survey is brief, requiring no more than 10 minutes of your time. Please be assured that your responses will be kept confidential.

Your participation in this phase of our research project would be greatly appreciated. We request that you complete and return your questionnaire in the postage-paid, self-addressed envelope by Friday, August 23, 1991. The results from the completed project will be gladly provided upon your request. Thank you for your consideration.

[Signatures]

Paula Fink Orsini, M.S., R.Ph.
Doctoral Candidate
Pharmaceutical Administration
The Ohio State University

Dey S. Pathak, B.A.
Chairman & Merrell Dow Professor
Pharmaceutical Administration
The Ohio State University

Robert E. Burnkrant, Ph.D.
Professor
Marketing
The Ohio State University

John J. Kennedy, Ph.D.
Professor
Education Services and Research
The Ohio State University
INTRODUCTION

Adverse drug events (ADEs) occur frequently in most physicians' practices and have a wide range of manifestations. Some are minor, require little or no intervention, and may even remain undetected. Others are serious, resulting in drug therapy, hospitalization or its prolongation, or even death. ADEs are classified as "labeled", expected or listed in the package insert, and "unlabeled", unexpected or not listed in the package insert.

When an ADE occurs in a patient, a physician may exercise several options. The physician may file a report with the manufacturer, a hospital's drug surveillance program, the FDA, a pharmaceutical representative, a specialized registry (e.g. U.S.P.), or do nothing. The physician may also decide to submit an anecdotal report or an article to the professional literature.

This study pertains specifically to physicians' decision to report or not to report serious ADEs directly to the FDA via the FDA's Spontaneous Reporting System (SRS). The SRS program consists of physicians' written completion of FDA's preprinted reporting form (FDA Form 1639).

As you read the following questions, please consider each one in terms of your decision to report a serious ADE to the FDA. According to the FDA, a serious ADE is "fatal or life-threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly, cancer, or overdose" (FDA, 1989).

INSTRUCTIONS FOR SCALES

In the questionnaire you are about to fill out, we ask questions which make use of rating scales with seven places. You are to make a check mark in the place that best describes your opinion. For example, if you were asked to rate "The weather in Portland" on a good-bad scale, you should use the scale as follows:

If you think the weather in Portland is extremely good, then you would place your mark as follows:

The weather in Portland is

good: extremely quite slightly neither slightly quite extremely bad

If you think the weather in Portland is quite bad, then you would place your mark as follows:

The weather in Portland is

good: extremely quite slightly neither slightly quite extremely bad
If you think the weather in Portland is *neither good nor bad*, then you would place your mark as follows:

The weather in Portland is

**good**: __ __ __ __ __ __ ___ **bad**

**extremely quite slightly neither slightly quite extremely**

In making your ratings, please remember the following points:

1. **Place your marks in the MIDDLE OF SPACES, not on the boundaries:**
   
   [Sample layout]

2. **Be sure you answer all items. Please do not omit any items.**
3. **Do not put more than one check mark on a single scale.**
4. **Your answers pertain only to YOUR decision to report SERIOUS ADEs, either LABELED or UNLABELED, to the FDA.**

A SERIOUS ADE is one that is "fatal or life-threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly, cancer, or overdose".

1. **My reporting the next serious ADE occurring in my practice to the FDA will be**

   **good**: __ __ __ __ __ __ __ __ __ __ **bad**

   **extremely quite slightly neither slightly quite extremely**

   **harmful**: __ __ __ __ __ __ __ __ __ __ **beneficial**

   **extremely quite slightly neither slightly quite extremely**

   **desirable**: __ __ __ __ __ __ __ __ __ __ **undesirable**

   **extremely quite slightly neither slightly quite extremely**

   **worthless**: __ __ __ __ __ __ __ __ __ __ **valuable**

   **extremely quite slightly neither slightly quite extremely**
2. In my view, the FDA is
worth-______:______:______:______:______:______:______:______:valuable
less extremely quite slightly neither slightly quite extremely
good _____:______:______:______:______:______:______:______:bad
extremely quite slightly neither slightly quite extremely
harm-______:______:______:______:______:______:______:______:beneficial
ful extremely quite slightly neither slightly quite extremely
useful _____:______:______:______:______:______:______:______:useless
extremely quite slightly neither slightly quite extremely

3. My reporting the next serious ADE occurring in my practice to the FDA
would help the FDA develop a more complete ADE data base.
likely ______:______:______:______:______:______:______:______:unlikely
extremely quite slightly neither slightly quite extremely

4. My reporting the next serious ADE occurring in my practice to the FDA
would discourage the use of borderline or high-risk drugs.
likely ______:______:______:______:______:______:______:______:unlikely
extremely quite slightly neither slightly quite extremely

5. My reporting the next serious ADE occurring in my practice to the FDA
would encourage the FDA to scrutinize the drug.
likely ______:______:______:______:______:______:______:______:unlikely
extremely quite slightly neither slightly quite extremely

6. My reporting the next serious ADE occurring in my practice to the FDA
would help prevent damaging ADEs.
likely ______:______:______:______:______:______:______:______:unlikely
extremely quite slightly neither slightly quite extremely

7. My reporting the next serious ADE occurring in my practice to the FDA
would help fulfill my obligation to practice good medicine.
likely ______:______:______:______:______:______:______:______:unlikely
extremely quite slightly neither slightly quite extremely
8. My reporting the next serious ADE occurring in my practice to the FDA would take too much time.

likely ______:_______:_______:_______:_______:_______ unlikely
extremely quite slightly neither slightly quite extremely

9. My reporting the next serious ADE occurring in my practice to the FDA would involve too much "paperwork".

likely ______:_______:_______:_______:_______:_______ unlikely
extremely quite slightly neither slightly quite extremely

10. My reporting the next serious ADE occurring in my practice to the FDA would pose a legal threat to my practice.

likely ______:_______:_______:_______:_______:_______ unlikely
extremely quite slightly neither slightly quite extremely

11. Helping the FDA develop a more complete ADE database is

good ______:_______:_______:_______:_______:_______ bad
extremely quite slightly neither slightly quite extremely

12. Discouraging the use of borderline or high-risk drugs is

good ______:_______:_______:_______:_______:_______ bad
extremely quite slightly neither slightly quite extremely

13. Encouraging the FDA to scrutinize a drug is

good ______:_______:_______:_______:_______:_______ bad
extremely quite slightly neither slightly quite extremely

14. Helping to prevent damaging ADEs is

good ______:_______:_______:_______:_______:_______ bad
extremely quite slightly neither slightly quite extremely

15. Helping to fulfill my obligation to practice good medicine is

good ______:_______:_______:_______:_______:_______ bad
extremely quite slightly neither slightly quite extremely
16. Taking too much time reporting a serious ADE is

good extremely quite slightly neither slightly quite extremely bad

17. Having too much "paperwork" is

good extremely quite slightly neither slightly quite extremely bad

18. Posing a legal threat to my practice is

good extremely quite slightly neither slightly quite extremely bad

19. Most people who are important to me would expect me to report the next serious ADE occurring in my practice to the FDA.

likely extremely quite slightly neither slightly quite extremely unlikely

20. The FDA would expect me to report the next serious ADE occurring in my practice to them.

likely extremely quite slightly neither slightly quite extremely unlikely

21. Medical organizations to which I belong would expect me to report the next serious ADE occurring in my practice to the FDA.

likely extremely quite slightly neither slightly quite extremely unlikely

22. Specialty practice organizations to which I belong would expect me to report the next serious ADE occurring in my practice to the FDA.

likely extremely quite slightly neither slightly quite extremely unlikely

23. My colleagues would expect me to report the next serious ADE occurring in my practice to the FDA.

likely extremely quite slightly neither slightly quite extremely unlikely
24. Pharmaceutical manufacturers, including their sales representatives, would expect me to report the next serious ADE occurring in my practice to the FDA.

likely extremely quite slightly neither slightly quite extremely unlikely

25. When it comes to medical issues, I think I should do what most people who are important to me expect me to do.

likely extremely quite slightly neither slightly quite extremely unlikely

26. When it comes to medical issues, I think I should do what the FDA expects me to do.

likely extremely quite slightly neither slightly quite extremely unlikely

27. When it comes to medical issues, I think I should do what the medical organizations to which I belong expect me to do.

likely extremely quite slightly neither slightly quite extremely unlikely

28. When it comes to medical issues, I think I should do what the specialty practice organizations to which I belong expect me to do.

likely extremely quite slightly neither slightly quite extremely unlikely

29. When it comes to medical issues, I think I should do what my colleagues expect me to do.

likely extremely quite slightly neither slightly quite extremely unlikely

30. When it comes to medical issues, I think I should do what pharmaceutical manufacturers, including their sales representatives, expect me to do.

likely extremely quite slightly neither slightly quite extremely unlikely
31. My practice includes hospitalized patients. (Check one)
   ___ YES (Proceed to next question)
   ___ NO (Skip to Question 36)

32. Hospital licensing agencies (e.g. JCAHO) would expect me to report the next serious ADE occurring in my practice to the FDA.
   likely _____:_____:_____:_____:_____:____:____:_____ unlikely
   extremely quite slightly neither slightly quite extremely

33. Committees in hospitals in which I have admitting or staff privileges would expect me to report the next serious ADE occurring in my practice to the FDA.
   likely _____:_____:_____:_____:_____:____:____:_____ unlikely
   extremely quite slightly neither slightly quite extremely

34. When it comes to medical issues, I think I should do what hospital licensing agencies (e.g. JCAHO) expect me to do.
   likely _____:_____:_____:_____:_____:____:____:_____ unlikely
   extremely quite slightly neither slightly quite extremely

35. When it comes to medical issues, I think I should do what committees in hospitals in which I have admitting or staff privileges expect me to do.
   likely _____:_____:_____:_____:_____:____:____:_____ unlikely
   extremely quite slightly neither slightly quite extremely

36. When the next serious ADE occurs in my practice, I will feel obligated to report it to the FDA.
   likely _____:_____:_____:_____:_____:____:____:_____ unlikely
   extremely quite slightly neither slightly quite extremely

37. When the next serious ADE occurs in my practice, I will have the time to report it to the FDA.
   likely _____:_____:_____:_____:_____:____:____:_____ unlikely
   extremely quite slightly neither slightly quite extremely
38. When the next serious ADE occurs in my practice, I will have the ability to report it to the FDA.

likely ______:_______:_______:_______:_______:_______ unlikely
extremely quite slightly neither slightly quite extremely

39. When the next serious ADE occurs in my practice, I will feel motivated to report it to the FDA.

likely ______:_______:_______:_______:_______:_______ unlikely
extremely quite slightly neither slightly quite extremely

40. When the next serious ADE occurs in my practice, the FDA's reporting form will be accessible to me.

likely ______:_______:_______:_______:_______:_______ unlikely
extremely quite slightly neither slightly quite extremely

41. When the next serious ADE occurs in my practice, reporting assistance will be available to me.

likely ______:_______:_______:_______:_______:_______ unlikely
extremely quite slightly neither slightly quite extremely

42. For me to report the next serious ADE occurring in my practice to the FDA is:

easy ______:_______:_______:_______:_______:_______ difficult
extremely quite slightly neither slightly quite extremely

43. If I wanted to, I could report the next serious ADE occurring in my practice to the FDA.

likely ______:_______:_______:_______:_______:_______ unlikely
extremely quite slightly neither slightly quite extremely

44. It is up to me whether or not I report the next serious ADE occurring in my practice to the FDA.

true ______:_______:_______:_______:_______:_______ false
extremely quite slightly neither slightly quite extremely

45. When the next serious ADE occurs in my practice, whether or not I report it to the FDA is

completely ______:_______:_______:_______:_______:_______ not at all
under my control

under my control
Questions 46-51 use the terms "facilitate" and "prevent" in describing how certain factors affect your executing an action. If a factor "facilitates", it actually improves or enhances your control over reporting to the FDA. Conversely, a factor which "prevents" impedes or impairs your control over reporting.

46. In terms of affecting my actual reporting, feeling obligated to report to the FDA would
facilitate ____________________________ prevent ____________________________

47. In terms of affecting my actual reporting, having the time to report to the FDA would
facilitate ____________________________ prevent ____________________________

48. In terms of affecting my actual reporting, having the ability to report to the FDA would
facilitate ____________________________ prevent ____________________________

49. In terms of affecting my actual reporting, feeling motivated to report to the FDA would
facilitate ____________________________ prevent ____________________________

50. In terms of affecting my actual reporting, an accessible reporting form would
facilitate ____________________________ prevent ____________________________

51. In terms of affecting my actual reporting, available reporting assistance would
facilitate ____________________________ prevent ____________________________

52. I intend to report the next serious ADE occurring in my practice to the FDA.
likely ____________________________ unlikely ____________________________
extremely quite slightly neither slightly quite extremely
53. When the next serious ADE occurs in my practice, I will try to report it to the FDA.


54. Before today, were you aware that the FDA maintains a spontaneous reporting system in which physicians submit written documentation of ADEs occurring in their practice to the FDA? (please check one)

_____ YES  _____ NO  _____ NOT SURE

55. How many serious ADEs have occurred in your practice during the following time periods? How many serious ADEs did you report to the FDA? (Please provide the number of ADEs on each line)

Within the past:  6 months  1 year  2 years

Number of serious ADEs occurring

Number of serious ADEs reported to the FDA

56. When did the last serious ADE occur in your practice? When did you last report a serious ADE to the FDA? (Please provide a number for each question)

Last serious ADE occurred

Last serious ADE reported to the FDA

Not applicable

______(yrs) or ______(mos)  ______(yrs) or ______(mos)  _____

57. What proportion of your practice is in-patient versus out-patient?

In-patient (%)  Out-patient (%)  Total (%)  Not Applicable

______ %  +  ______ %  =  100 %  _______
58. Are you a provider for a managed health care plan?

_____ YES  _____ NO  _____ NOT SURE

59. What is the approximate size of the largest hospital in which you have admitting or staff privileges? (Please check one)

_____ 1000 +
_____ 751 - 1000
_____ 501 - 750
_____ 250 - 500
_____ < 250
_____ Not applicable

60. Please divide the time you spend daily with teaching, research, and patient care activities.

_____ % teaching
_____ % research
_____ % patient care
_____ % other (please specify below)

100 %

61. Are you male or female (Please check one)  _____ Male  _____ Female

62. How many years have you been a licensed physician? (Please check one)

_____ < 5 years
_____ 5 - 15 years
_____ 15 - 30 years
_____ 30 +

63. What is your specialty of practice?


Thank you for completing this survey. Please return in the enclosed postage-paid, self-addressed envelope by Wednesday, September 18, 1991.

If you would like a copy of the results from this project upon its completion, please provide your name and address below.
APPENDIX C

OSUHP MEDICAL DIRECTOR: SUPPORT MEMOS
MEMORANDUM

To: Physicians of Ohio State University Health Plan

From: Patricia C. Temple, M.D.
Medical Director, OSUHP

Subject: OSU Research Project

The life blood of a university are its students and their research projects. Paula Funk Orsini is a doctoral candidate in the College of Pharmacy. Her research investigates the reasons a practicing physician might or might not report serious adverse drug events. Ten to fifteen minutes of your time will help her evaluate the many factors involved in physicians' decision to report adverse drug events to the FDA. Thank you for your cooperation.
APPENDIX D

SECOND WAVE COVER LETTER
Dear Doctor:

Two weeks ago you were asked to participate in an important research project being conducted at The Ohio State University. This project's goal is to gather information regarding physicians' decision to report or not to report serious adverse drug events to the FDA.

The enclosed survey is developed from a pilot study conducted with physicians. Your completion of this questionnaire, requiring no more than 10 minutes of your time, is critical to our research. Please be assured that your responses will be kept confidential.

Again, we ask for your assistance with this research endeavor. We request that you return the completed questionnaire by Wednesday, September 18, 1991. If you have already responded to our invitation, please ignore this second request and accept our sincere appreciation.
APPENDIX E

INPUT CORRELATION MATRICES: CBSI AND CB MODELS
TABLE 20

INPUT CORRELATION MATRIX: CONTROL BELIEF MODEL (N = 474)*

<table>
<thead>
<tr>
<th></th>
<th>AB1</th>
<th>AB2</th>
<th>AB3</th>
<th>AB4</th>
<th>AO1</th>
<th>AO2</th>
</tr>
</thead>
<tbody>
<tr>
<td>AB1</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AB2</td>
<td>0.534</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AB3</td>
<td>0.443</td>
<td>0.443</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AB4</td>
<td>0.424</td>
<td>0.536</td>
<td>0.390</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AO1</td>
<td>0.103</td>
<td>0.107</td>
<td>0.176</td>
<td>0.260</td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>AO2</td>
<td>0.186</td>
<td>0.178</td>
<td>0.172</td>
<td>0.249</td>
<td>0.480</td>
<td>1.000</td>
</tr>
<tr>
<td>AO3</td>
<td>0.132</td>
<td>0.187</td>
<td>0.149</td>
<td>0.242</td>
<td>0.628</td>
<td>0.510</td>
</tr>
<tr>
<td>AO4</td>
<td>0.092</td>
<td>0.076</td>
<td>0.235</td>
<td>0.175</td>
<td>0.395</td>
<td>0.543</td>
</tr>
<tr>
<td>BE1</td>
<td>0.313</td>
<td>0.301</td>
<td>0.303</td>
<td>0.354</td>
<td>0.282</td>
<td>0.285</td>
</tr>
<tr>
<td>BE2</td>
<td>0.158</td>
<td>0.101</td>
<td>0.098</td>
<td>0.170</td>
<td>0.171</td>
<td>0.158</td>
</tr>
<tr>
<td>BE3</td>
<td>0.197</td>
<td>0.179</td>
<td>0.145</td>
<td>0.263</td>
<td>0.347</td>
<td>0.275</td>
</tr>
<tr>
<td>BE4</td>
<td>0.333</td>
<td>0.307</td>
<td>0.320</td>
<td>0.381</td>
<td>0.200</td>
<td>0.263</td>
</tr>
<tr>
<td>BE5</td>
<td>0.264</td>
<td>0.186</td>
<td>0.201</td>
<td>0.286</td>
<td>0.313</td>
<td>0.268</td>
</tr>
<tr>
<td>BE6</td>
<td>0.138</td>
<td>0.109</td>
<td>0.143</td>
<td>0.160</td>
<td>0.062</td>
<td>0.034</td>
</tr>
<tr>
<td>BE7</td>
<td>0.135</td>
<td>0.062</td>
<td>0.126</td>
<td>0.158</td>
<td>0.087</td>
<td>0.098</td>
</tr>
<tr>
<td>BE8</td>
<td>0.074</td>
<td>0.199</td>
<td>0.129</td>
<td>0.172</td>
<td>0.128</td>
<td>0.106</td>
</tr>
<tr>
<td>SNMC</td>
<td>0.084</td>
<td>0.055</td>
<td>0.130</td>
<td>0.067</td>
<td>0.046</td>
<td>0.066</td>
</tr>
<tr>
<td>NM1</td>
<td>0.217</td>
<td>0.109</td>
<td>0.208</td>
<td>0.163</td>
<td>0.195</td>
<td>0.256</td>
</tr>
<tr>
<td>NM2</td>
<td>0.161</td>
<td>0.099</td>
<td>0.176</td>
<td>0.159</td>
<td>0.113</td>
<td>0.069</td>
</tr>
<tr>
<td>NM3</td>
<td>0.148</td>
<td>0.048</td>
<td>0.167</td>
<td>0.105</td>
<td>0.097</td>
<td>0.065</td>
</tr>
<tr>
<td>NM4</td>
<td>0.199</td>
<td>0.117</td>
<td>0.212</td>
<td>0.188</td>
<td>0.144</td>
<td>0.156</td>
</tr>
<tr>
<td>NM5</td>
<td>0.170</td>
<td>0.133</td>
<td>0.184</td>
<td>0.195</td>
<td>0.127</td>
<td>0.125</td>
</tr>
<tr>
<td>NM6</td>
<td>0.180</td>
<td>0.156</td>
<td>0.162</td>
<td>0.181</td>
<td>0.076</td>
<td>0.108</td>
</tr>
<tr>
<td>NM7</td>
<td>-0.044</td>
<td>-0.051</td>
<td>0.002</td>
<td>-0.034</td>
<td>-0.090</td>
<td>0.011</td>
</tr>
<tr>
<td>CB1</td>
<td>0.369</td>
<td>0.263</td>
<td>0.296</td>
<td>0.347</td>
<td>0.171</td>
<td>0.204</td>
</tr>
<tr>
<td>CB2</td>
<td>0.265</td>
<td>0.154</td>
<td>0.166</td>
<td>0.209</td>
<td>0.158</td>
<td>0.158</td>
</tr>
<tr>
<td>CB3</td>
<td>0.289</td>
<td>0.222</td>
<td>0.213</td>
<td>0.290</td>
<td>0.124</td>
<td>0.141</td>
</tr>
<tr>
<td>CB4</td>
<td>0.383</td>
<td>0.256</td>
<td>0.276</td>
<td>0.380</td>
<td>0.195</td>
<td>0.185</td>
</tr>
<tr>
<td>CB5</td>
<td>0.213</td>
<td>0.106</td>
<td>0.155</td>
<td>0.194</td>
<td>0.100</td>
<td>0.141</td>
</tr>
<tr>
<td>CB6</td>
<td>0.198</td>
<td>0.109</td>
<td>0.123</td>
<td>0.199</td>
<td>0.124</td>
<td>0.128</td>
</tr>
<tr>
<td>GC1</td>
<td>0.213</td>
<td>0.130</td>
<td>0.130</td>
<td>0.184</td>
<td>0.106</td>
<td>0.158</td>
</tr>
<tr>
<td>GC2</td>
<td>0.211</td>
<td>0.197</td>
<td>0.156</td>
<td>0.227</td>
<td>0.074</td>
<td>0.048</td>
</tr>
<tr>
<td>GC3</td>
<td>0.026</td>
<td>0.054</td>
<td>0.047</td>
<td>-0.051</td>
<td>0.003</td>
<td>0.073</td>
</tr>
<tr>
<td>GC4</td>
<td>0.114</td>
<td>0.110</td>
<td>0.102</td>
<td>-0.025</td>
<td>0.046</td>
<td>0.092</td>
</tr>
<tr>
<td>I1</td>
<td>0.411</td>
<td>0.312</td>
<td>0.271</td>
<td>0.396</td>
<td>0.178</td>
<td>0.178</td>
</tr>
<tr>
<td>I2</td>
<td>0.411</td>
<td>0.306</td>
<td>0.292</td>
<td>0.395</td>
<td>0.151</td>
<td>0.214</td>
</tr>
</tbody>
</table>

* Missing values generated by SAS before calculating correlations with PRELIS.
Table 20 (continued)

<table>
<thead>
<tr>
<th></th>
<th>AO3</th>
<th>AO4</th>
<th>BE1</th>
<th>BE2</th>
<th>BE3</th>
<th>BE4</th>
</tr>
</thead>
<tbody>
<tr>
<td>AO3</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AO4</td>
<td>0.388</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE1</td>
<td>0.260</td>
<td>0.256</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE2</td>
<td>0.180</td>
<td>0.168</td>
<td>0.319</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE3</td>
<td>0.256</td>
<td>0.261</td>
<td>0.424</td>
<td>0.392</td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>BE4</td>
<td>0.208</td>
<td>0.236</td>
<td>0.497</td>
<td>0.254</td>
<td>0.362</td>
<td>1.000</td>
</tr>
<tr>
<td>BE5</td>
<td>0.215</td>
<td>0.209</td>
<td>0.444</td>
<td>0.425</td>
<td>0.548</td>
<td>0.370</td>
</tr>
<tr>
<td>BE6</td>
<td>0.085</td>
<td>0.074</td>
<td>0.143</td>
<td>0.070</td>
<td>0.125</td>
<td>0.164</td>
</tr>
<tr>
<td>BE7</td>
<td>0.114</td>
<td>0.080</td>
<td>0.209</td>
<td>0.078</td>
<td>0.133</td>
<td>0.223</td>
</tr>
<tr>
<td>BE8</td>
<td>0.227</td>
<td>0.055</td>
<td>0.117</td>
<td>-0.022</td>
<td>0.032</td>
<td>0.154</td>
</tr>
<tr>
<td>SNMC</td>
<td>0.068</td>
<td>0.021</td>
<td>0.158</td>
<td>0.216</td>
<td>0.181</td>
<td>0.199</td>
</tr>
<tr>
<td>NM1</td>
<td>0.152</td>
<td>0.185</td>
<td>0.290</td>
<td>0.308</td>
<td>0.308</td>
<td>0.267</td>
</tr>
<tr>
<td>NM2</td>
<td>0.072</td>
<td>0.038</td>
<td>0.197</td>
<td>0.169</td>
<td>0.193</td>
<td>0.331</td>
</tr>
<tr>
<td>NM3</td>
<td>0.063</td>
<td>0.012</td>
<td>0.182</td>
<td>0.123</td>
<td>0.186</td>
<td>0.299</td>
</tr>
<tr>
<td>NM4</td>
<td>0.083</td>
<td>0.095</td>
<td>0.224</td>
<td>0.236</td>
<td>0.236</td>
<td>0.306</td>
</tr>
<tr>
<td>NM5</td>
<td>0.080</td>
<td>0.081</td>
<td>0.238</td>
<td>0.245</td>
<td>0.190</td>
<td>0.322</td>
</tr>
<tr>
<td>NM6</td>
<td>0.102</td>
<td>0.081</td>
<td>0.174</td>
<td>0.174</td>
<td>0.200</td>
<td>0.272</td>
</tr>
<tr>
<td>NM7</td>
<td>-0.123</td>
<td>-0.001</td>
<td>0.009</td>
<td>0.081</td>
<td>0.007</td>
<td>0.043</td>
</tr>
<tr>
<td>CB1</td>
<td>0.146</td>
<td>0.182</td>
<td>0.338</td>
<td>0.281</td>
<td>0.299</td>
<td>0.530</td>
</tr>
<tr>
<td>CB2</td>
<td>0.115</td>
<td>0.148</td>
<td>0.258</td>
<td>0.201</td>
<td>0.243</td>
<td>0.344</td>
</tr>
<tr>
<td>CB3</td>
<td>0.098</td>
<td>0.151</td>
<td>0.324</td>
<td>0.101</td>
<td>0.198</td>
<td>0.377</td>
</tr>
<tr>
<td>CB4</td>
<td>0.150</td>
<td>0.199</td>
<td>0.373</td>
<td>0.238</td>
<td>0.306</td>
<td>0.543</td>
</tr>
<tr>
<td>CB5</td>
<td>0.111</td>
<td>0.158</td>
<td>0.250</td>
<td>0.024</td>
<td>0.184</td>
<td>0.235</td>
</tr>
<tr>
<td>CB6</td>
<td>0.125</td>
<td>0.098</td>
<td>0.231</td>
<td>0.068</td>
<td>0.218</td>
<td>0.238</td>
</tr>
<tr>
<td>GC1</td>
<td>0.107</td>
<td>0.136</td>
<td>0.274</td>
<td>0.136</td>
<td>0.232</td>
<td>0.278</td>
</tr>
<tr>
<td>GC2</td>
<td>0.044</td>
<td>0.098</td>
<td>0.259</td>
<td>0.074</td>
<td>0.189</td>
<td>0.247</td>
</tr>
<tr>
<td>GC3</td>
<td>0.123</td>
<td>0.095</td>
<td>0.072</td>
<td>-0.006</td>
<td>0.004</td>
<td>0.090</td>
</tr>
<tr>
<td>GC4</td>
<td>0.144</td>
<td>0.102</td>
<td>0.082</td>
<td>-0.017</td>
<td>0.041</td>
<td>0.094</td>
</tr>
<tr>
<td>I1</td>
<td>0.103</td>
<td>0.178</td>
<td>0.367</td>
<td>0.250</td>
<td>0.350</td>
<td>0.519</td>
</tr>
<tr>
<td>I2</td>
<td>0.111</td>
<td>0.197</td>
<td>0.385</td>
<td>0.249</td>
<td>0.328</td>
<td>0.522</td>
</tr>
</tbody>
</table>
Table 20 (continued)

<table>
<thead>
<tr>
<th></th>
<th>BE5</th>
<th>BE6</th>
<th>BE7</th>
<th>BE8</th>
<th>SNMC</th>
<th>NM1</th>
</tr>
</thead>
<tbody>
<tr>
<td>BE5</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE6</td>
<td>0.176</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE7</td>
<td>0.211</td>
<td>0.682</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE8</td>
<td>0.113</td>
<td>0.137</td>
<td>0.163</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNMC</td>
<td>0.181</td>
<td>-0.016</td>
<td>0.029</td>
<td>-0.004</td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>NM1</td>
<td>0.335</td>
<td>0.112</td>
<td>0.189</td>
<td>-0.004</td>
<td>0.567</td>
<td>1.000</td>
</tr>
<tr>
<td>NM2</td>
<td>0.240</td>
<td>0.082</td>
<td>0.118</td>
<td>0.076</td>
<td>0.398</td>
<td>0.458</td>
</tr>
<tr>
<td>NM3</td>
<td>0.220</td>
<td>0.091</td>
<td>0.160</td>
<td>0.065</td>
<td>0.368</td>
<td>0.455</td>
</tr>
<tr>
<td>NM4</td>
<td>0.293</td>
<td>0.074</td>
<td>0.112</td>
<td>0.058</td>
<td>0.578</td>
<td>0.686</td>
</tr>
<tr>
<td>NM5</td>
<td>0.268</td>
<td>0.104</td>
<td>0.147</td>
<td>0.061</td>
<td>0.504</td>
<td>0.620</td>
</tr>
<tr>
<td>NM6</td>
<td>0.250</td>
<td>0.140</td>
<td>0.186</td>
<td>0.095</td>
<td>0.554</td>
<td>0.561</td>
</tr>
<tr>
<td>NM7</td>
<td>0.019</td>
<td>-0.023</td>
<td>-0.007</td>
<td>-0.043</td>
<td>0.143</td>
<td>0.144</td>
</tr>
<tr>
<td>CB1</td>
<td>0.374</td>
<td>0.181</td>
<td>0.244</td>
<td>0.120</td>
<td>0.250</td>
<td>0.373</td>
</tr>
<tr>
<td>CB2</td>
<td>0.277</td>
<td>0.401</td>
<td>0.417</td>
<td>0.131</td>
<td>0.163</td>
<td>0.346</td>
</tr>
<tr>
<td>CB3</td>
<td>0.252</td>
<td>0.254</td>
<td>0.248</td>
<td>0.177</td>
<td>0.092</td>
<td>0.208</td>
</tr>
<tr>
<td>CB4</td>
<td>0.325</td>
<td>0.223</td>
<td>0.264</td>
<td>0.115</td>
<td>0.180</td>
<td>0.309</td>
</tr>
<tr>
<td>CB5</td>
<td>0.196</td>
<td>0.222</td>
<td>0.327</td>
<td>0.155</td>
<td>0.036</td>
<td>0.202</td>
</tr>
<tr>
<td>CB6</td>
<td>0.206</td>
<td>0.214</td>
<td>0.251</td>
<td>0.130</td>
<td>0.016</td>
<td>0.163</td>
</tr>
<tr>
<td>GC1</td>
<td>0.237</td>
<td>0.285</td>
<td>0.374</td>
<td>0.098</td>
<td>-0.005</td>
<td>0.228</td>
</tr>
<tr>
<td>GC2</td>
<td>0.203</td>
<td>0.101</td>
<td>0.167</td>
<td>0.110</td>
<td>0.093</td>
<td>0.155</td>
</tr>
<tr>
<td>GC3</td>
<td>0.004</td>
<td>0.013</td>
<td>0.048</td>
<td>0.147</td>
<td>-0.085</td>
<td>-0.064</td>
</tr>
<tr>
<td>GC4</td>
<td>0.063</td>
<td>0.039</td>
<td>0.073</td>
<td>0.155</td>
<td>-0.007</td>
<td>-0.012</td>
</tr>
<tr>
<td>I1</td>
<td>0.347</td>
<td>0.130</td>
<td>0.232</td>
<td>0.082</td>
<td>0.201</td>
<td>0.289</td>
</tr>
<tr>
<td>I2</td>
<td>0.359</td>
<td>0.122</td>
<td>0.231</td>
<td>0.091</td>
<td>0.187</td>
<td>0.293</td>
</tr>
</tbody>
</table>
Table 20 (continued)

<table>
<thead>
<tr>
<th></th>
<th>NM2</th>
<th>NM3</th>
<th>NM4</th>
<th>NM5</th>
<th>NM6</th>
<th>NM7</th>
</tr>
</thead>
<tbody>
<tr>
<td>NM2</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NM3</td>
<td>0.844</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NM4</td>
<td>0.541</td>
<td>0.542</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NM5</td>
<td>0.464</td>
<td>0.462</td>
<td>0.808</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NM6</td>
<td>0.504</td>
<td>0.473</td>
<td>0.651</td>
<td>0.613</td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>NM7</td>
<td>0.117</td>
<td>0.087</td>
<td>0.152</td>
<td>0.094</td>
<td>0.211</td>
<td>1.000</td>
</tr>
<tr>
<td>CB1</td>
<td>0.461</td>
<td>0.433</td>
<td>0.392</td>
<td>0.380</td>
<td>0.378</td>
<td>-0.022</td>
</tr>
<tr>
<td>CB2</td>
<td>0.269</td>
<td>0.278</td>
<td>0.348</td>
<td>0.303</td>
<td>0.276</td>
<td>0.000</td>
</tr>
<tr>
<td>CB3</td>
<td>0.280</td>
<td>0.253</td>
<td>0.208</td>
<td>0.240</td>
<td>0.270</td>
<td>-0.028</td>
</tr>
<tr>
<td>CB4</td>
<td>0.330</td>
<td>0.323</td>
<td>0.349</td>
<td>0.366</td>
<td>0.341</td>
<td>-0.069</td>
</tr>
<tr>
<td>CB5</td>
<td>0.193</td>
<td>0.202</td>
<td>0.195</td>
<td>0.200</td>
<td>0.232</td>
<td>-0.101</td>
</tr>
<tr>
<td>CB6</td>
<td>0.191</td>
<td>0.199</td>
<td>0.206</td>
<td>0.199</td>
<td>0.225</td>
<td>-0.041</td>
</tr>
<tr>
<td>GC1</td>
<td>0.210</td>
<td>0.224</td>
<td>0.261</td>
<td>0.261</td>
<td>0.204</td>
<td>-0.015</td>
</tr>
<tr>
<td>GC2</td>
<td>0.228</td>
<td>0.193</td>
<td>0.142</td>
<td>0.210</td>
<td>0.169</td>
<td>-0.014</td>
</tr>
<tr>
<td>GC3</td>
<td>-0.025</td>
<td>-0.045</td>
<td>-0.116</td>
<td>-0.088</td>
<td>0.028</td>
<td>0.022</td>
</tr>
<tr>
<td>GC4</td>
<td>0.000</td>
<td>0.003</td>
<td>-0.044</td>
<td>-0.032</td>
<td>0.034</td>
<td>-0.027</td>
</tr>
<tr>
<td>I1</td>
<td>0.328</td>
<td>0.305</td>
<td>0.317</td>
<td>0.350</td>
<td>0.332</td>
<td>-0.001</td>
</tr>
<tr>
<td>I2</td>
<td>0.334</td>
<td>0.298</td>
<td>0.312</td>
<td>0.336</td>
<td>0.301</td>
<td>0.015</td>
</tr>
</tbody>
</table>
Table 20 (continued)

<table>
<thead>
<tr>
<th></th>
<th>CB1</th>
<th>CB2</th>
<th>CB3</th>
<th>CB4</th>
<th>CB5</th>
<th>CB6</th>
</tr>
</thead>
<tbody>
<tr>
<td>CB1</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CB2</td>
<td>0.433</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CB3</td>
<td>0.366</td>
<td>0.468</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CB4</td>
<td>0.700</td>
<td>0.467</td>
<td>0.521</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CB5</td>
<td>0.297</td>
<td>0.413</td>
<td>0.446</td>
<td>0.409</td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>CB6</td>
<td>0.288</td>
<td>0.379</td>
<td>0.322</td>
<td>0.384</td>
<td>0.625</td>
<td>1.000</td>
</tr>
<tr>
<td>GC1</td>
<td>0.336</td>
<td>0.510</td>
<td>0.384</td>
<td>0.422</td>
<td>0.612</td>
<td>0.625</td>
</tr>
<tr>
<td>GC2</td>
<td>0.349</td>
<td>0.339</td>
<td>0.448</td>
<td>0.347</td>
<td>0.343</td>
<td>0.338</td>
</tr>
<tr>
<td>GC3</td>
<td>-0.026</td>
<td>0.022</td>
<td>0.120</td>
<td>-0.021</td>
<td>0.030</td>
<td>0.079</td>
</tr>
<tr>
<td>GC4</td>
<td>0.017</td>
<td>0.091</td>
<td>0.189</td>
<td>0.059</td>
<td>0.117</td>
<td>0.072</td>
</tr>
<tr>
<td>I1</td>
<td>0.693</td>
<td>0.446</td>
<td>0.424</td>
<td>0.741</td>
<td>0.335</td>
<td>0.325</td>
</tr>
<tr>
<td>I2</td>
<td>0.689</td>
<td>0.426</td>
<td>0.416</td>
<td>0.712</td>
<td>0.305</td>
<td>0.273</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>GC1</th>
<th>GC2</th>
<th>GC3</th>
<th>GC4</th>
<th>I1</th>
<th>I2</th>
</tr>
</thead>
<tbody>
<tr>
<td>GC1</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GC2</td>
<td>0.369</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GC3</td>
<td>0.033</td>
<td>0.144</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GC4</td>
<td>0.065</td>
<td>0.211</td>
<td>0.588</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I1</td>
<td>0.374</td>
<td>0.417</td>
<td>-0.019</td>
<td>0.021</td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>I2</td>
<td>0.327</td>
<td>0.402</td>
<td>0.003</td>
<td>0.055</td>
<td>0.888</td>
<td>1.000</td>
</tr>
</tbody>
</table>
TABLE 21

INPUT CORRELATION MATRIX: CBSI MODEL (N = 474)*

<table>
<thead>
<tr>
<th></th>
<th>AB1</th>
<th>AB2</th>
<th>AB3</th>
<th>AB4</th>
<th>AO1</th>
<th>AO2</th>
</tr>
</thead>
<tbody>
<tr>
<td>AB1</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AB2</td>
<td>0.534</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AB3</td>
<td>0.443</td>
<td>0.443</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AB4</td>
<td>0.424</td>
<td>0.536</td>
<td>0.390</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AO1</td>
<td>0.103</td>
<td>0.107</td>
<td>0.176</td>
<td>0.260</td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>AO2</td>
<td>0.186</td>
<td>0.178</td>
<td>0.172</td>
<td>0.249</td>
<td>0.480</td>
<td>1.000</td>
</tr>
<tr>
<td>AO3</td>
<td>0.132</td>
<td>0.187</td>
<td>0.149</td>
<td>0.242</td>
<td>0.628</td>
<td>0.510</td>
</tr>
<tr>
<td>AO4</td>
<td>0.092</td>
<td>0.076</td>
<td>0.235</td>
<td>0.175</td>
<td>0.395</td>
<td>0.543</td>
</tr>
<tr>
<td>BE1</td>
<td>0.313</td>
<td>0.301</td>
<td>0.303</td>
<td>0.354</td>
<td>0.282</td>
<td>0.285</td>
</tr>
<tr>
<td>BE2</td>
<td>0.158</td>
<td>0.101</td>
<td>0.098</td>
<td>0.170</td>
<td>0.171</td>
<td>0.158</td>
</tr>
<tr>
<td>BE3</td>
<td>0.197</td>
<td>0.179</td>
<td>0.145</td>
<td>0.263</td>
<td>0.347</td>
<td>0.275</td>
</tr>
<tr>
<td>BE4</td>
<td>0.333</td>
<td>0.307</td>
<td>0.320</td>
<td>0.381</td>
<td>0.200</td>
<td>0.263</td>
</tr>
<tr>
<td>BE5</td>
<td>0.264</td>
<td>0.186</td>
<td>0.201</td>
<td>0.286</td>
<td>0.313</td>
<td>0.268</td>
</tr>
<tr>
<td>BE6</td>
<td>0.138</td>
<td>0.109</td>
<td>0.143</td>
<td>0.160</td>
<td>0.062</td>
<td>0.034</td>
</tr>
<tr>
<td>BE7</td>
<td>0.135</td>
<td>0.062</td>
<td>0.126</td>
<td>0.158</td>
<td>0.087</td>
<td>0.098</td>
</tr>
<tr>
<td>BE8</td>
<td>0.074</td>
<td>0.199</td>
<td>0.129</td>
<td>0.172</td>
<td>0.128</td>
<td>0.106</td>
</tr>
<tr>
<td>SNMC</td>
<td>0.084</td>
<td>0.055</td>
<td>0.130</td>
<td>0.067</td>
<td>0.046</td>
<td>0.066</td>
</tr>
<tr>
<td>NM1</td>
<td>0.217</td>
<td>0.109</td>
<td>0.208</td>
<td>0.163</td>
<td>0.195</td>
<td>0.256</td>
</tr>
<tr>
<td>NM2</td>
<td>0.161</td>
<td>0.099</td>
<td>0.176</td>
<td>0.159</td>
<td>0.113</td>
<td>0.069</td>
</tr>
<tr>
<td>NM3</td>
<td>0.148</td>
<td>0.048</td>
<td>0.167</td>
<td>0.105</td>
<td>0.097</td>
<td>0.065</td>
</tr>
<tr>
<td>NM4</td>
<td>0.199</td>
<td>0.117</td>
<td>0.212</td>
<td>0.188</td>
<td>0.144</td>
<td>0.156</td>
</tr>
<tr>
<td>NM5</td>
<td>0.170</td>
<td>0.133</td>
<td>0.184</td>
<td>0.195</td>
<td>0.127</td>
<td>0.125</td>
</tr>
<tr>
<td>NM6</td>
<td>0.180</td>
<td>0.156</td>
<td>0.162</td>
<td>0.181</td>
<td>0.076</td>
<td>0.108</td>
</tr>
<tr>
<td>NM7</td>
<td>-0.044</td>
<td>-0.051</td>
<td>0.002</td>
<td>-0.034</td>
<td>-0.090</td>
<td>0.011</td>
</tr>
<tr>
<td>CS1</td>
<td>0.317</td>
<td>0.235</td>
<td>0.278</td>
<td>0.314</td>
<td>0.210</td>
<td>0.217</td>
</tr>
<tr>
<td>CS2</td>
<td>0.386</td>
<td>0.253</td>
<td>0.279</td>
<td>0.368</td>
<td>0.155</td>
<td>0.189</td>
</tr>
<tr>
<td>CS3</td>
<td>0.316</td>
<td>0.265</td>
<td>0.249</td>
<td>0.318</td>
<td>0.085</td>
<td>0.147</td>
</tr>
<tr>
<td>CS4</td>
<td>0.218</td>
<td>0.152</td>
<td>0.141</td>
<td>0.181</td>
<td>0.132</td>
<td>0.142</td>
</tr>
<tr>
<td>CS5</td>
<td>0.236</td>
<td>0.108</td>
<td>0.160</td>
<td>0.206</td>
<td>0.090</td>
<td>0.128</td>
</tr>
<tr>
<td>CS6</td>
<td>0.184</td>
<td>0.088</td>
<td>0.119</td>
<td>0.188</td>
<td>0.136</td>
<td>0.119</td>
</tr>
<tr>
<td>GC1</td>
<td>0.213</td>
<td>0.130</td>
<td>0.130</td>
<td>0.184</td>
<td>0.106</td>
<td>0.158</td>
</tr>
<tr>
<td>GC2</td>
<td>0.211</td>
<td>0.197</td>
<td>0.156</td>
<td>0.227</td>
<td>0.074</td>
<td>0.048</td>
</tr>
<tr>
<td>GC3</td>
<td>0.026</td>
<td>0.054</td>
<td>0.047</td>
<td>-0.051</td>
<td>0.003</td>
<td>0.073</td>
</tr>
<tr>
<td>GC4</td>
<td>0.114</td>
<td>0.110</td>
<td>0.102</td>
<td>-0.025</td>
<td>0.046</td>
<td>0.092</td>
</tr>
<tr>
<td>I1</td>
<td>0.411</td>
<td>0.312</td>
<td>0.271</td>
<td>0.396</td>
<td>0.178</td>
<td>0.178</td>
</tr>
<tr>
<td>I2</td>
<td>0.411</td>
<td>0.306</td>
<td>0.292</td>
<td>0.395</td>
<td>0.151</td>
<td>0.214</td>
</tr>
</tbody>
</table>

* Missing values generated by SAS before calculating with PRELIS.
Table 21 (continued)

<table>
<thead>
<tr>
<th></th>
<th>AO3</th>
<th>AO4</th>
<th>BE1</th>
<th>BE2</th>
<th>BE3</th>
<th>BE4</th>
</tr>
</thead>
<tbody>
<tr>
<td>AO3</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AO4</td>
<td>0.388</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE1</td>
<td>0.260</td>
<td>0.256</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE2</td>
<td>0.180</td>
<td>0.168</td>
<td>0.319</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE3</td>
<td>0.256</td>
<td>0.261</td>
<td>0.424</td>
<td>0.392</td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>BE4</td>
<td>0.208</td>
<td>0.236</td>
<td>0.497</td>
<td>0.254</td>
<td>0.362</td>
<td>1.000</td>
</tr>
<tr>
<td>BE5</td>
<td>0.215</td>
<td>0.209</td>
<td>0.444</td>
<td>0.425</td>
<td>0.548</td>
<td>0.370</td>
</tr>
<tr>
<td>BE6</td>
<td>0.085</td>
<td>0.074</td>
<td>0.143</td>
<td>0.070</td>
<td>0.125</td>
<td>0.164</td>
</tr>
<tr>
<td>BE7</td>
<td>0.114</td>
<td>0.080</td>
<td>0.209</td>
<td>0.078</td>
<td>0.133</td>
<td>0.223</td>
</tr>
<tr>
<td>BE8</td>
<td>0.223</td>
<td>0.055</td>
<td>0.117</td>
<td>-0.022</td>
<td>0.032</td>
<td>0.154</td>
</tr>
<tr>
<td>SNMC</td>
<td>0.068</td>
<td>0.021</td>
<td>0.158</td>
<td>0.216</td>
<td>0.181</td>
<td>0.199</td>
</tr>
<tr>
<td>NM1</td>
<td>0.152</td>
<td>0.185</td>
<td>0.290</td>
<td>0.308</td>
<td>0.308</td>
<td>0.267</td>
</tr>
<tr>
<td>NM2</td>
<td>0.072</td>
<td>0.038</td>
<td>0.197</td>
<td>0.169</td>
<td>0.193</td>
<td>0.331</td>
</tr>
<tr>
<td>NM3</td>
<td>0.063</td>
<td>0.012</td>
<td>0.182</td>
<td>0.123</td>
<td>0.186</td>
<td>0.299</td>
</tr>
<tr>
<td>NM4</td>
<td>0.083</td>
<td>0.095</td>
<td>0.224</td>
<td>0.236</td>
<td>0.236</td>
<td>0.306</td>
</tr>
<tr>
<td>NM5</td>
<td>0.080</td>
<td>0.081</td>
<td>0.238</td>
<td>0.245</td>
<td>0.190</td>
<td>0.322</td>
</tr>
<tr>
<td>NM6</td>
<td>0.102</td>
<td>0.081</td>
<td>0.174</td>
<td>0.174</td>
<td>0.200</td>
<td>0.272</td>
</tr>
<tr>
<td>NM7</td>
<td>-0.123</td>
<td>-0.001</td>
<td>0.009</td>
<td>0.081</td>
<td>0.007</td>
<td>0.043</td>
</tr>
<tr>
<td>CS1</td>
<td>0.181</td>
<td>0.221</td>
<td>0.354</td>
<td>0.283</td>
<td>0.381</td>
<td>0.456</td>
</tr>
<tr>
<td>CS2</td>
<td>0.143</td>
<td>0.192</td>
<td>0.372</td>
<td>0.219</td>
<td>0.301</td>
<td>0.522</td>
</tr>
<tr>
<td>CS3</td>
<td>0.074</td>
<td>0.172</td>
<td>0.329</td>
<td>0.159</td>
<td>0.226</td>
<td>0.383</td>
</tr>
<tr>
<td>CS4</td>
<td>0.135</td>
<td>0.146</td>
<td>0.282</td>
<td>0.215</td>
<td>0.235</td>
<td>0.292</td>
</tr>
<tr>
<td>CS5</td>
<td>0.113</td>
<td>0.154</td>
<td>0.248</td>
<td>0.031</td>
<td>0.182</td>
<td>0.232</td>
</tr>
<tr>
<td>CS6</td>
<td>0.135</td>
<td>0.094</td>
<td>0.221</td>
<td>0.073</td>
<td>0.232</td>
<td>0.221</td>
</tr>
<tr>
<td>GC1</td>
<td>0.107</td>
<td>0.136</td>
<td>0.274</td>
<td>0.136</td>
<td>0.232</td>
<td>0.278</td>
</tr>
<tr>
<td>GC2</td>
<td>0.044</td>
<td>0.098</td>
<td>0.259</td>
<td>0.074</td>
<td>0.189</td>
<td>0.247</td>
</tr>
<tr>
<td>GC3</td>
<td>0.123</td>
<td>0.095</td>
<td>0.072</td>
<td>-0.006</td>
<td>0.004</td>
<td>0.090</td>
</tr>
<tr>
<td>GC4</td>
<td>0.144</td>
<td>0.102</td>
<td>0.082</td>
<td>-0.017</td>
<td>0.041</td>
<td>0.094</td>
</tr>
<tr>
<td>I1</td>
<td>0.103</td>
<td>0.178</td>
<td>0.367</td>
<td>0.250</td>
<td>0.350</td>
<td>0.519</td>
</tr>
<tr>
<td>I2</td>
<td>0.111</td>
<td>0.197</td>
<td>0.385</td>
<td>0.249</td>
<td>0.328</td>
<td>0.522</td>
</tr>
</tbody>
</table>
Table 21 (continued)

<table>
<thead>
<tr>
<th></th>
<th>BE5</th>
<th>BE6</th>
<th>BE7</th>
<th>BE8</th>
<th>SNMC</th>
<th>NM1</th>
</tr>
</thead>
<tbody>
<tr>
<td>BE5</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE6</td>
<td>0.176</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE7</td>
<td>0.211</td>
<td>0.682</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BE8</td>
<td>0.113</td>
<td>0.137</td>
<td>0.163</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SNMC</td>
<td>0.181</td>
<td>-0.016</td>
<td>0.029</td>
<td>-0.004</td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>NM1</td>
<td>0.335</td>
<td>0.112</td>
<td>0.189</td>
<td>-0.004</td>
<td>0.567</td>
<td>1.000</td>
</tr>
<tr>
<td>NM2</td>
<td>0.240</td>
<td>0.082</td>
<td>0.118</td>
<td>0.076</td>
<td>0.398</td>
<td>0.458</td>
</tr>
<tr>
<td>NM3</td>
<td>0.220</td>
<td>0.091</td>
<td>0.160</td>
<td>0.065</td>
<td>0.368</td>
<td>0.455</td>
</tr>
<tr>
<td>NM4</td>
<td>0.293</td>
<td>0.074</td>
<td>0.112</td>
<td>0.058</td>
<td>0.578</td>
<td>0.686</td>
</tr>
<tr>
<td>NM5</td>
<td>0.268</td>
<td>0.104</td>
<td>0.147</td>
<td>0.061</td>
<td>0.504</td>
<td>0.620</td>
</tr>
<tr>
<td>NM6</td>
<td>0.250</td>
<td>0.140</td>
<td>0.186</td>
<td>0.095</td>
<td>0.554</td>
<td>0.561</td>
</tr>
<tr>
<td>NM7</td>
<td>0.019</td>
<td>-0.023</td>
<td>-0.007</td>
<td>-0.043</td>
<td>0.143</td>
<td>0.144</td>
</tr>
<tr>
<td>CS1</td>
<td>0.445</td>
<td>0.220</td>
<td>0.290</td>
<td>0.141</td>
<td>0.232</td>
<td>0.409</td>
</tr>
<tr>
<td>CS2</td>
<td>0.354</td>
<td>0.188</td>
<td>0.225</td>
<td>0.081</td>
<td>0.180</td>
<td>0.345</td>
</tr>
<tr>
<td>CS3</td>
<td>0.270</td>
<td>0.198</td>
<td>0.200</td>
<td>0.182</td>
<td>0.100</td>
<td>0.229</td>
</tr>
<tr>
<td>CS4</td>
<td>0.283</td>
<td>0.344</td>
<td>0.347</td>
<td>0.171</td>
<td>0.219</td>
<td>0.345</td>
</tr>
<tr>
<td>CS5</td>
<td>0.233</td>
<td>0.201</td>
<td>0.306</td>
<td>0.156</td>
<td>0.056</td>
<td>0.211</td>
</tr>
<tr>
<td>CS6</td>
<td>0.238</td>
<td>0.192</td>
<td>0.229</td>
<td>0.115</td>
<td>0.033</td>
<td>0.175</td>
</tr>
<tr>
<td>GC1</td>
<td>0.237</td>
<td>0.285</td>
<td>0.374</td>
<td>0.098</td>
<td>-0.005</td>
<td>0.228</td>
</tr>
<tr>
<td>GC2</td>
<td>0.203</td>
<td>0.101</td>
<td>0.167</td>
<td>0.110</td>
<td>0.093</td>
<td>0.155</td>
</tr>
<tr>
<td>GC3</td>
<td>0.004</td>
<td>0.013</td>
<td>0.048</td>
<td>0.147</td>
<td>-0.085</td>
<td>-0.064</td>
</tr>
<tr>
<td>GC4</td>
<td>0.063</td>
<td>0.039</td>
<td>0.073</td>
<td>0.155</td>
<td>-0.007</td>
<td>-0.012</td>
</tr>
<tr>
<td>I1</td>
<td>0.347</td>
<td>0.130</td>
<td>0.232</td>
<td>0.082</td>
<td>0.201</td>
<td>0.289</td>
</tr>
<tr>
<td>I2</td>
<td>0.359</td>
<td>0.122</td>
<td>0.231</td>
<td>0.091</td>
<td>0.187</td>
<td>0.293</td>
</tr>
</tbody>
</table>
Table 21 (continued)

<table>
<thead>
<tr>
<th></th>
<th>NM2</th>
<th>NM3</th>
<th>NM4</th>
<th>NM5</th>
<th>NM6</th>
<th>NM7</th>
</tr>
</thead>
<tbody>
<tr>
<td>NM2</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NM3</td>
<td>0.844</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NM4</td>
<td>0.541</td>
<td>0.542</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NM5</td>
<td>0.464</td>
<td>0.462</td>
<td>0.808</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NM6</td>
<td>0.504</td>
<td>0.473</td>
<td>0.651</td>
<td>0.613</td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>NM7</td>
<td>0.117</td>
<td>0.087</td>
<td>0.152</td>
<td>0.094</td>
<td>0.211</td>
<td>1.000</td>
</tr>
<tr>
<td>CS1</td>
<td>0.421</td>
<td>0.409</td>
<td>0.387</td>
<td>0.417</td>
<td>0.347</td>
<td>-0.013</td>
</tr>
<tr>
<td>CS2</td>
<td>0.372</td>
<td>0.336</td>
<td>0.365</td>
<td>0.402</td>
<td>0.333</td>
<td>-0.085</td>
</tr>
<tr>
<td>CS3</td>
<td>0.321</td>
<td>0.262</td>
<td>0.255</td>
<td>0.313</td>
<td>0.277</td>
<td>-0.014</td>
</tr>
<tr>
<td>CS4</td>
<td>0.269</td>
<td>0.268</td>
<td>0.372</td>
<td>0.325</td>
<td>0.287</td>
<td>-0.001</td>
</tr>
<tr>
<td>CS5</td>
<td>0.208</td>
<td>0.209</td>
<td>0.212</td>
<td>0.214</td>
<td>0.241</td>
<td>-0.096</td>
</tr>
<tr>
<td>CS6</td>
<td>0.199</td>
<td>0.206</td>
<td>0.231</td>
<td>0.216</td>
<td>0.228</td>
<td>-0.030</td>
</tr>
<tr>
<td>GC1</td>
<td>0.210</td>
<td>0.224</td>
<td>0.261</td>
<td>0.261</td>
<td>0.204</td>
<td>-0.015</td>
</tr>
<tr>
<td>GC2</td>
<td>0.228</td>
<td>0.193</td>
<td>0.142</td>
<td>0.210</td>
<td>0.169</td>
<td>-0.014</td>
</tr>
<tr>
<td>GC3</td>
<td>-0.025</td>
<td>-0.045</td>
<td>-0.116</td>
<td>-0.088</td>
<td>0.028</td>
<td>0.022</td>
</tr>
<tr>
<td>GC4</td>
<td>0.000</td>
<td>0.003</td>
<td>-0.044</td>
<td>-0.032</td>
<td>0.034</td>
<td>-0.027</td>
</tr>
<tr>
<td>I1</td>
<td>0.328</td>
<td>0.305</td>
<td>0.317</td>
<td>0.350</td>
<td>0.332</td>
<td>-0.001</td>
</tr>
<tr>
<td>I2</td>
<td>0.334</td>
<td>0.298</td>
<td>0.312</td>
<td>0.336</td>
<td>0.301</td>
<td>0.015</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>CS1</th>
<th>CS2</th>
<th>CS3</th>
<th>CS4</th>
<th>CS5</th>
<th>CS6</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS1</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CS2</td>
<td>0.666</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CS3</td>
<td>0.452</td>
<td>0.585</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CS4</td>
<td>0.423</td>
<td>0.404</td>
<td>0.415</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CS5</td>
<td>0.325</td>
<td>0.395</td>
<td>0.365</td>
<td>0.348</td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>CS6</td>
<td>0.264</td>
<td>0.346</td>
<td>0.271</td>
<td>0.310</td>
<td>0.602</td>
<td>1.000</td>
</tr>
<tr>
<td>GC1</td>
<td>0.314</td>
<td>0.415</td>
<td>0.335</td>
<td>0.451</td>
<td>0.591</td>
<td>0.603</td>
</tr>
<tr>
<td>GC2</td>
<td>0.316</td>
<td>0.404</td>
<td>0.443</td>
<td>0.264</td>
<td>0.346</td>
<td>0.319</td>
</tr>
<tr>
<td>GC3</td>
<td>-0.010</td>
<td>0.005</td>
<td>0.092</td>
<td>-0.013</td>
<td>0.022</td>
<td>0.052</td>
</tr>
<tr>
<td>GC4</td>
<td>0.092</td>
<td>0.087</td>
<td>0.146</td>
<td>0.057</td>
<td>0.122</td>
<td>0.060</td>
</tr>
<tr>
<td>I1</td>
<td>0.575</td>
<td>0.710</td>
<td>0.441</td>
<td>0.332</td>
<td>0.318</td>
<td>0.309</td>
</tr>
<tr>
<td>I2</td>
<td>0.576</td>
<td>0.693</td>
<td>0.485</td>
<td>0.335</td>
<td>0.301</td>
<td>0.267</td>
</tr>
</tbody>
</table>
Table 21 (continued)

<table>
<thead>
<tr>
<th></th>
<th>CB1</th>
<th>CB2</th>
<th>CB3</th>
<th>CB4</th>
<th>CB5</th>
<th>CB6</th>
</tr>
</thead>
<tbody>
<tr>
<td>CB1</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CB2</td>
<td>0.433</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CB3</td>
<td>0.366</td>
<td>0.468</td>
<td>1.000</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CB4</td>
<td>0.700</td>
<td>0.467</td>
<td>0.521</td>
<td>1.000</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CB5</td>
<td>0.297</td>
<td>0.413</td>
<td>0.446</td>
<td>0.409</td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td>CB6</td>
<td>0.288</td>
<td>0.379</td>
<td>0.322</td>
<td>0.384</td>
<td>0.625</td>
<td>1.000</td>
</tr>
<tr>
<td>GC1</td>
<td>0.336</td>
<td>0.510</td>
<td>0.384</td>
<td>0.422</td>
<td>0.612</td>
<td>0.625</td>
</tr>
<tr>
<td>GC2</td>
<td>0.349</td>
<td>0.339</td>
<td>0.448</td>
<td>0.347</td>
<td>0.343</td>
<td>0.338</td>
</tr>
<tr>
<td>GC3</td>
<td>-0.026</td>
<td>0.022</td>
<td>0.120</td>
<td>-0.021</td>
<td>0.030</td>
<td>0.079</td>
</tr>
<tr>
<td>GC4</td>
<td>0.017</td>
<td>0.091</td>
<td>0.189</td>
<td>0.059</td>
<td>0.117</td>
<td>0.072</td>
</tr>
<tr>
<td>I1</td>
<td>0.693</td>
<td>0.446</td>
<td>0.424</td>
<td>0.741</td>
<td>0.335</td>
<td>0.325</td>
</tr>
<tr>
<td>I2</td>
<td>0.689</td>
<td>0.426</td>
<td>0.416</td>
<td>0.712</td>
<td>0.305</td>
<td>0.273</td>
</tr>
</tbody>
</table>
LIST OF REFERENCES


Ajzen, Icek, and Driver, B.E. "Application of the theory of planned behavior to leisure choice: A preliminary investigation." Unpublished manuscript Department of Psychology, University of Massachusetts at Amherst.


365


Caranasos, George J.; Stewart, Ronald B.; and Clugg, Leighton E. "Drug-induced illness leading to hospitalization." *Journal of the American Medical Society* 228 (May 6, 1974): 713-717.


Col, Nananda; Fanale, James E.; and Kronholm, Penelope. "The role of medication noncompliance and adverse drug reactions in hospitalizations of the elderly." *Archives of Internal Medicine* 150 (Apr, 1990): 841-845.


Kennedy, Dianne L.; Goetsch, Roger A.; and Dreis, Michael W. "Uses and reported adverse effects of new chemical entities." American Journal of Hospital Pharmacy 46 (Mar, 1989): 558-564.


Rogers, Audrey S.; Israil, Ebenezer; Smith, Craig R.; Levine, David; McBean, A. Marshall; Valente, Carmine; and Faich, Gerald. "Physician knowledge, attitudes, and behavior related to reporting adverse drug events." *Archives of Internal Medicine* 148 (Jul, 1988): 1596-1600.


