1-1-2011

Physician decision criteria regarding omega-3 dietary supplements

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This is to certify that the doctoral study by

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2014

Abstract

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MBA, Centenary College of Louisiana, 1987

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Doctoral Study Submitted in Partial Fulfillment

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March 2014

Abstract

American Heart Association officials and other expert cardiologists recommend omega-3 (n-3) dietary supplementation for the secondary prevention of cardiovascular disease, a prevalent health problem in the United States. Physicians' lack of understanding of possible n-3 preventive health benefits results in underprescribing n-3 dietary supplements and lower n-3 dietary supplement product sales. N-3 dietary supplement marketers do not understand physician n-3 prescribing decision criteria enough to optimize high-impact communication to physicians to increase n-3 dietary supplement product use. The purpose of this phenomenological research study was to improve n-3 marketers' understanding of how physicians reach decisions to prescribe or recommend products including n-3 dietary supplements. Argyris' ladder of inference theory provided the study framework to facilitate understanding physicians' decision criteria. Rich data collected and analyzed from 20 primary care physician interviews in Kentucky, Indiana, and Tennessee revealed physicians use similar decision criteria for drugs and n-3s. Three essential influencers of physician decisions included clinical evidence, personal experience, and cost. Other influencers were opinions of peers, pharmaceutical representatives, samples, direct-to-consumer advertising, and knowledge of dietary supplements. Study outcomes may inform pharmaceutical marketers regarding presentation of clinical evidence, cost emphasis, and pharmaceutical representative skills and may facilitate competitive advantage for n-3 marketers. The social benefit of this study is improved physician understanding of n-3s may result in more accurate and appropriate prescribing to augment positive health outcomes.

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Acknowledgments

Many thanks to my committee members for their guidance, especially my Chair, Dr. Robert Miller; Second Chair, Dr. Michael Ewald; and methodologists Dr. Gene Fusch and Dr. Doug Campbell, and URR Dr. Judith Blando. Special thanks also go to my classmate and friend, Dr. Gregory Banks. Most importantly, I thank my wife, Mary, for her unwavering and incalculable support.

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Section1: Foundation of the Study

The American Heart Association recommends omega-3 (n-3) dietary supplementation for the secondary prevention of cardiovascular disease (Lee, O'Keefe, Lavie, Marchiolo, & Harris, 2008) but physicians' lack of understanding of possible n-3 preventive health benefits results in the underprescribing of n-3 dietary supplements and lower n-3 dietary supplement product sales (Dickinson, Shao, Boyon, & Franco, 2011). N-3 dietary supplement marketers do not understand physician n-3 prescribing decision criteria. The purpose of this study was to explore the ladder of inference physicians cognitively ascend when deciding if they will recommend or prescribe omega-3 fatty acid (n-3) dietary supplements to their patients. The ladder of inference is a decision criteria model theory (Argyris, 1976) consisting of sequential, logical steps individuals take to reach logical conclusions. By analyzing each decision logic step among study subjects (physicians), I discovered and gained a better understanding of physician decision processes and concluded critical communication links useful for n-3 marketers to help solve marketers' business problem of low physician cognizance of n-3 health benefits and their commitment to n-3 utilization. Adams, Kohlmeier, and Zeisel, (2010) supported the lack of sufficient physician education regarding n-3s. The business problem included the difficulty in communicating the complex mechanisms of n-3s to physicians and subsequently from physicians to their patients.

In this study, I explained the study topic, applied business research to a business problem, specified the research study plan including its design and methods, and described the potential benefits the research study would generate for business and

society. In this research study, I followed the Onwuegbuzie et al.'s (2012) exemplar for teaching and learning qualitative research. According to Onwuegbuzie et al., the qualitative research process involves 13 distinct and dynamic components: (a) determining the study goal, (b) formulating research objectives, (c) determining rationale, (d) determining purpose of research, (e) defining the research question, (f) selecting the sample design and size, (g) selecting research design, (h) collecting data, (i) analyzing data, (j) validating data, (k) interpreting data, (l) writing the final report, and (m) reformulating the research question as appropriate. I addressed and satisfied these 13 qualitative componentsin the following six subsections: (a) background, (b) problem statement, (c) purpose statement, (e) data research methods and reliability, (f) data analysis and validity, and (g) application to business practice and implications for social change.

Background

Although cardiologists and knowledgeable primary care physicians can understand n-3 health benefits, the business problem for n-3 marketers is a deficiency in understanding why many primary care physicians do not regularly recommend n-3 dietary supplements to their patients (Dickinson, Boyon, & Shao, 2009; Dickinson, Shao, Boyon, & Franco, 2011). In one survey of 109 U.S. medical schools, 79% of instructors reported deficient dietary supplement education; only 30% of medical schools had a separate dietary supplement course (Adams, Kohlmeier, & Zeisel, 2010).

Regarding the background of n-3 safety and efficacy, many but not all clinical study investigators support n-3 dietary supplements for reducing cardiovascular disease

epidemiology. For example, Siddiqui, Harvey, Ruzmetov, Miller, and Zaloga (2009) reported n-3 dietary supplements counter health consequences of red meat consumption containing arachidonic acid (AA), an omega-6 (n-6) fatty acid that exacerbates systemic inflammation and clogs arteries in humans (atherosclerosis is the number one cause of death in the United States; Venes, 2009). Investigators such as Cottin, Sanders, and Hall (2011) and Lee, O'Keefe, Lavie, Marchiolo, and Harris (2008) explained n-3s, specifically docosahexanoic acid (DHA) and eicosapentanoic acid (EPA), compete with arachidonic acid and other n-6s for phospholipid membrane positions in human cells. These investigators concluded ample EPA and DHA consumption mitigate n-6 health consequences. Other supporting evidence includes the Food and Drug Administration (FDA) approval of Lovaza, a prescription n-3 supplement containing 465 mg EPA and 375 mg DHA for hypertriglyceridemia (Serebruany et al., 2011).

Other clinical trial results support the positive preventive impact of consuming sufficient amounts of quality n-3s. For example, medical investigators reported the n-3 long-chain (LC) polyunsaturated fatty acids (PUFA): EPA and DHA, abundant in marine fish, act to lower lipid blood levels to reduce cardiac events and decrease the progression of atherosclerosis (Kopecky, Rossmeisl, Flachs, & Kuda, 2009, p. 361). Kopecky et al. (2009) linked adipose tissue to the beneficial effects of n-3s on health, explaining a reduction in the inflammation of adipose tissue and improved glucose and lipid metabolism. Kopecky et al. further concluded the dietary intake of fish oil or concentrates containing both EPA and DHA improves lipid metabolism and insulin excretion and

regulation, ancillary benefits not addressed in this study. They concluded that in human subjects, n-3s achieve steady-state serum levels within 1 month.

In another example, Mayo Clinic Proceedings cardiologists reported results from thousands of published clinical trials over three decades indicated cardiovascular protective effects (Lee et al., 2008) reported clinical trial evidence (n = 32,000) of cardiovascular events reduction in 19–45% of patients ingesting n-3s versus placebo. Lee et al. cited the results of three specific large trials (n = 32,000) demonstrating the positive benefits associated with n-3s, either from oily fish or fish oil gel caps (Lee et al., 2008). Simopoulos (2011) noted how human beings evolved on a diet with a ratio of n-6s to n-3s of approximately 1:1 whereas in modern times, Westerners consume diets with ratios of 10:1 to 25:1, (n-6s to n-3s). Simopoulos also noted how industrialized societies increase energy intake while decreasing energy expenditure and consume a diet rich in saturated fat, n-6s, trans-fatty acids, and decreased n-3s. Mirmiran et al. (2012) cited a substantial body of evidence to support a balanced dietary ratio of n-6:n-3 for the prevention of cardiovascular disease and lower incidence of metabolic syndrome.

The American Heart Association recommends a diet of fatty fish at least twice per week (London et al., 2011). London et al. (2011) noted patients with coronary heart disease should consume more than 1 gram daily of combined EPA and DHA. In addition, London et al. also opined indisputable evidence exists n-3s have a positive impact on cardiac electric activity. The American Heart Association (AHA) has endorsed n-3s for secondary prevention of cardiovascular disease and the AHA, American College of Cardiology, and the European Society of Cardiology found the n-3 evidence strong

enough to issue public recommendations for increased n-3 dietary intake (Lee et al. 2008).

Some investigators reported conflicting results and offer opposing viewpoints of n-3 safety and efficacy. Regarding n-3 safety, De Caterina (2011) noted the AHA advised caution with respect to fish contaminants. Brasky et al. (2013) linked high n-3 blood levels to increased prostate cancer. Other investigators attributed prostate carcinogenesis and other cancers to environmental toxins potentially in fish oil and unpurified fish oil supplements including pesticides, trace minerals, or methylmercury (Ginsberg & Toal, 2009; Mullins & Loeb, 2012).

Other investigators expressed skepticism regarding n-3 efficacy. For example, Chen et al. (2011) determined no significant differences in lowered epidemiology of sudden cardiac death, cardiac death, and all-cause mortality. Whelan, Gouffon, and Zhao (2012) determined one substance converted by the body to EPA (SDA) was not effective in lowering triglycerides, HDL, or LDL levels. Borghi and Pareo (2012) raised skepticism regarding the efficacy of n-3s in reducing ventricular arrhythmias. Vlablik, Prusikova, Snejdrlova, and Zlatohlavek (2009) raised the possibility n-3 dietary supplementation may raise undesirable low-density lipoprotein (LDL) cholesterol levels when used in high doses for patients with hypertriglyceridemia.

In a large study (n = 12,356), Bosch et al. (2012) evaluated high-risk patients including those with impaired fasting glucose, impaired glucose tolerance, or diabetes and concluded n-3s had no effect on reducing cardiovascular events in this high-risk group. Kromhout, Giltay, and Geleijnse (2010) determined low dose n-3 dietary

supplementation (226 mg EPA and 150 mg DHA) did not reduce fatal or nonfatal cardiovascular events. In a quantitative method analysis of 20 studies, Rizos, Ntzani, Bika, Kostapanos, and Elisaf (2012) determined no statistically significant correlation between n-3 supplementation and lower risk of all-cause mortality, cardiac death, sudden death, MI, or stroke. It is important for n-3 marketers to understand objectively although substantial clinical evidence exists to support n-3 efficacy and safety, a number of investigators offer credible and contradictory evidence.

Perhaps because of this contradictory evidence or perhaps because physicians do not have sufficient knowledge, survey results indicated primary care physicians do not routinely recommend n-3 dietary supplements to patients (Dickinson, et al., 2011). Two studies reported most physicians acknowledged they did not have sufficient education regarding dietary supplements but expressed a desire to acquire more knowledge (Dickinson, et al., 2009). These findings provided the foundation for the problem statement in this study.

Problem Statement

Marketers of n-3s understand important cardiovascular disease statistics in the United States: More than 120,000 Americans under the age of 65 die prematurely from heart disease each year (Centers for Disease Control [CDC], 2011) and U.S. health care costs rose from $714 billion in 1990 to $2.3 trillion in 2008 (CDC, 2011). Health care cost increases may result from a deficiency in cardiovascular disease preventive medicine. Physicians understand cardiovascular consequences of high cholesterol and triglyceride blood levels. Although not all clinical investigators support the safety and

efficacy of n-3s, results from more than 100 clinical studies demonstrated reduced cholesterol and triglycerides after concentrated n-3 dietary supplementation (London et al., 2011).

The general business problem for pharmaceutical marketers is physicians' lack of understanding of possible n-3 preventive health benefits (Dickinson et al., 2009; Dickinson et al., 2011) resulting in the under-prescribing of n-3 dietary supplements and lower n-3 dietary supplement product sales. The specific business problem is n-3 marketers do not understand physician n-3 prescribing decision criteria so n-3 marketers can optimize high-impact communication to physicians to increase n-3 prescribing and n-3 dietary supplement product use.

Purpose Statement

The purpose of this phenomenological research study was to improve n-3 marketers' understanding of how physicians reach decisions to prescribe or recommend products including omega-3 (n-3) dietary supplements and which product characteristics may be the most important to physicians. I explored physicians' n-3 dietary supplement knowledge, and decision criteria (ladder of inference; Argyris, 1976). Understanding these complexities may help n-3 marketers to develop learning tools (predictors) to influence physician decisions (criteria) to recommend patient consumption of quality n-3s.

Appropriate for a qualitative phenomenological study design, I interviewed 20 primary care physicians located in Kentucky, Indiana, and Tennessee. Interviewing physicians was justified because of their opinion-leader statuses and influence over

patient health (Ashar & Rowland-Seymour, 2008). The marketing context study objective answered the primary research question to determine the n-3 ladder of inference physicians ascend. The business implication may facilitate n-3 marketers' understanding of physician customers' thinking and needs. An improved understanding by n-3 marketers may culminate in more effective n-3 marketing, clearer communication, and increased preventive medicine behaviors by physicians. Increased n-3 use among the general population may result in improved health, reduced cardiac disease, and reduced U.S. healthcare spending.

Nature of the Study

I used the qualitative method to gather data and analyze the data to find useful information and understand thought processes and decision criteria among physician subjects. Bertolotti and Tagliaventi (2007) employed qualitative methods to identify complex views, opinions, and perceptions of participants. According to Bertolotti and Tagliaventi, the purpose of a qualitative study is to identify themes and constructs among the words used by participants in response to open-ended questions. In this study, without prompting, all physician subjects used words to indicate they did have some knowledge of n-3 benefits preventing cardiovascular disease. Even so, I used words such as "Please tell me your opinion regarding…" to encourage open expression and opposing viewpoints.

According to Csordas, Dole, Tran, Strickland, and Storck (2010), interviewers should choose words based upon careful assessment of the pretext, subtext, and context interview factors. Pretext involves any previous conversations between interviewer and

study subject, and the possible influence of those conversations. Subtext refers to the influence of subjects' hidden agendas and relevant to this study, meant allowing subjects to voice their hidden agendas to support or reject n-3 safety and efficacy in the prevention of cardiovascular disease.

Regarding the context of the setting, I insisted upon a quiet, private interview room free of interruptions to protect the interview setting. Additional steps included carefully planning interview questions, electronically recording and transcribing data verbatim, and using detailed, descriptive text. I documented my personal bias in favor of n-3 efficacy and safety but described steps I took to prevent bias during interviews. I was careful not to contradict any physician subjects who questioned n-3 safety and efficacy.

Regarding data analysis, Bertolotti and Tagliaventi (2007) emphasized the importance of data analysis objectification, a critical element to support study validity. In this study I used inter-coder agreement, triangulation, peer review, and member checking to ensure study validity. The complexity of collected data did not necessitate coding software such as HyperRESEARCH (Textor & Hedrick, 2012) to facilitate coding efficiency and objectivity. Approved by an Institutional Review Board (IRB approval 05-29-13-0265406), one other coder and I worked independently but collaboratively to drive convergent and divergent themes from data collected from physician subjects (inter-coder agreement). The other coder signed a *Confidentiality Agreement* to protect subjects' anonymity and privacy.

I selected physician participants based upon their willingness to participate (access) and their open perspectives regarding diverse opinions. By description, these

criteria necessitated the inclusion of some physicians who already prescribed or recommended n-3s. Geographical scope, a willingness to set aside sufficient time without interruptions, and a private setting defined acceptable participant access criteria.

For data collection, I conducted personal interviews using a semistructured format to facilitate free expression by participants and allow clarifying questions. The data I collected was qualitative. Neuman (2011) observed a quantitative research method is appropriate for seeking numeric responses to narrow question responses. However, the rightness of understanding how physicians make decisions was achieved perhaps to a greater degree without quantitative measurement.

Before data collection, I validated the research interview instrument through one pilot test interview and used interviewing-the-investigator technique (Chenail, 2011) to determine realistic responses as well as improve interviewing skills. These preparatory steps were taken to enhance the trustworthiness of collected data and therefore improve the reliability and validity of coding, theme development, analysis, and study outcomes. After data collection and theme development, I sent identified themes and transcript excerpts to participants for the purposes of member-checking and triangulation. I protected the confidentiality of all participants and identified only the initial of the subject reviewing the document. The intent of this step was to enrich study validity, conformability, and outcomes significance. Approximately one-half of study subjects responded and all who responded affirmed document accuracy without revisions.

Research Question

Using the primary study question, I invited situational examination (contextual application) and expanded knowledge (Ellis & Levy, 2009). The answer shaped the strategy for n-3 marketers regarding how physicians make medical decisions using observable, selected data, and how they add personal meanings, assumptions, and conclusions to the data resulting in behavioral action. My primary research question was: For the purpose of marketing strategy, what is the ladder of inference physicians use to recommend n-3 dietary supplements?

The specific interview questions were:

1. Considering the previously explained ladder of inference and reflexive loop (Ayers, 2002), what processes do you go through to determine what products you will prescribe or what dietary supplements you will recommend?
2. What credible clinical evidence have you seen regarding fish oil dietary supplements?
3. What made the evidence credible or incredulous?
4. What are the risks of taking fish oil dietary supplements?
5. What are the risks regarding specific patient groups or disease states?
6. What are the important differences between quality fish oil dietary supplements and low quality fish oil dietary supplements?
7. What are right daily amounts of DHA and EPA?

8. If clinical evidence is credible and convincing regarding fish oil efficacy for health prevention for disease amelioration, what education and communication methods to physicians are best?
9. Similarly, what education and communication methods to patients are best?
10. Within the context of the ladder, please explain your present professional opinion regarding the health value of fish oil dietary supplements, specifically fish oil containing n-3s, for patients with no contraindications.
11. What are your prescribing or recommending practices regarding n-3 fatty acid dietary supplements and the priority of n-3 dietary supplements as compared with other dietary supplements (e.g., multivitamins, chondroitin, niacin)?
12. How influential are your peers' prescribing practices to your decisions?
13. When you speak with your peers, what percentage of them would you say are committed to frequently recommending omega-3s?
14. If all your patients took a high quality omega-3 every day, what would be the impact on your whole practice?
15. If all your patients took a high quality omega-3 every day, what would be the positive impact on U.S. healthcare costs?

Conceptual Framework

Physicians, in general, lack sufficient knowledge of dietary supplements, and in particular n-3s (Ashar, Rice, & Sisson, 2008), to discuss with confidence these substances with patients (Kemper, Amata-Kynvi, Dvorkin, Whelan, Woolf, Samuels, & Hibberd,

2003). I found no reference more recent than 2003, which supports a gap in the literature and the need for this study.

Ladder of inference theory (Argyris, 1976) provided a conceptual framework for deciphering and prioritizing the complex and competing factors influencing physicians' knowledge and willingness to recommend n-3s. Ladder of inference theory includes six ladder rungs as requisite steps leading from data to enacted behavior. These progressive, logical ladders are as follows: (a) observable data and experiences, (b) selected data from observable data, (c) assumptions based upon meanings added to data based upon cultural and personal experiences, (d) conclusions drawn from assumptions, (e) adopted beliefs about the world, and (f) actions taken based upon beliefs (Argyris, 1976). Using the ladder of inference model to guide interview questions added structure and meaning to physician subject responses. This structure also facilitated data coding, interpretation, and analysis. The ladder of inference theory facilitated physicians' self-understandings, helped identify needs for education and marketing purposes, and fostered efficiency when attempting to drive theme clarity and outcomes from the group upon member-checking follow-up.

Definition of Terms

Allopathic: A system of treating disease by inducing a pathological reaction antagonistic to the treated disease (Venes, 2009).

Atherosclerosis: Arterial disorder characterized by restricted blood flow from cholesterol-lipid-calcium deposits in the walls of arteries. Over time, arteries may become completely blocked. If a plaque ruptures within a blood vessel, the blood vessel

can close, and organs or tissues may infarct. Risk factors for atherosclerosis are tobacco abuse, diabetes mellitus, elevated blood lipid concentrations, hypertension, family history, male gender, menopause in women, microalbuminemia, chronic kidney disease, increased age, sedentary lifestyle, and obesity (Venes, 2009).

Atherogenesis: The formation of plaques beneath the membrane of artery linings (Venes, 2009).

Auto-ethnography: As the researcher, my experience automatically derives from a cultural connection or identification with the subject (Sergi & Hallin, 2011)

Complementary and alternative medicine (CAM): CAMs are alternative therapies to conventional treatments. Conventional treatments demonstrate efficacy and safety to achieve FDA approval. Complementary medicine indicates a therapy may be added to a conventional treatment. Alternative medicine implies a therapy other than a conventional treatment. The Cochrane Collaboration provides a classification of CAM treatments (Wieland, Manheimer, & Berman, 2011).

Chemotaxis: Cellular movement toward or away from chemical stimuli. The term *chemotaxis* primarily refers to phagocytic white blood cells (Venes, 2009).

Docosahexanoic acid (DHA): Long chain polyunsaturated n-3 (Venes, 2009).

Docosapentanoic acid (DPA): Long chain polyunsaturated n-3 fatty acid metabolized by the body into eicosapentanoic acid (EPA) (Whelan, 2009).

Eicosapentanoic acid: Long chain polyunsaturated n-3 fatty acid.

Essential fatty acid (EFA): A polyunsaturated fatty acid necessary in the diet for proper growth, maintenance, and bodily function. Diets deficient in EFAs may contribute

to changes in cell structure and enzyme function, resulting in decreased growth and other disorders. Symptoms include nail problems, brittle hair, dandruff, allergic conditions, dermatitis, and eczema in infants (Venes, 2009).

Homeopathic, homeopathy: Based upon the proposal that very dilute doses of extracts, medicines, or other substances producing symptoms of disease in healthy people will cure those diseases in affected patients (i.e., "like cures like"). Homeopathy differs from allopathy because homeopathy emphasizes the body healing itself (Venes, 2009).

Hypertriglyceridemia: A condition marked by too many triglycerides in the blood (Venes, 2009).

Ladder of inference: A mental model containing decision rungs, all of which are confirmable by others, except the bottom rung of observable data and experiences. Subsequent ascending rungs include *I Select Data* (from what a researcher can observe), *I Add Meanings* (cultural and personal), *I Make Assumptions* (based on the meanings the researcher adds), *I Draw Conclusions*, *I Adopt Beliefs* (about the world), and *I Take Actions* (based on the researcher's beliefs). An individual can unconsciously ascend the ladder quickly, perhaps too quickly, taking actions based upon established beliefs, triggered by observed data. This process is a reflexive loop (Ayers, 2002).

Momentary salience: the temporal influences of personal mood and environment affecting a decision (Weiss, Weiss, & Edwards, 2010)

Omega-3 fatty acids (n-3s): Essential fatty acids with double bonds at the third carbon away from the omega (methyl) end of the molecule (Venes, 2009).

Physician: An individual who successfully completed the prescribed curriculum of studies in a medical school officially recognized by the country of the medical school location, and who has acquired the requisite qualifications for licensure in the practice of medicine (Venes, 2009).

Preventive medicine: The branch of medicine to prevent disease and methods to increase power of patient and community to resist disease and prolong life (Venes, 2009).

Qi gong (qigong): The Chinese approach to healing based upon the harnessing of inner energy sources. Therapists employ movement, breathing exercises, meditation, and relaxation (Venes, 2009). In the medical field sometimes referred to as *qi* (Wieland et al., 2011).

Reflexive loop: Human reactive behavior where an individual interprets observed data selectively, biased by personal beliefs and experiences (Ayres, 2002).

Rigor: The process of identifying gaps between what was actually done versus a prescribed or standard method using a measurement approach throughout the analysis to assure accuracy and reduce the risk of shallow analysis (Zelik, Patterson, & Woods, 2010).

Stearidonic acid (SDA): An n-3 fatty acid with similar biological properties to EPA found in plant sources such as soybean oil, hemp seed oil, and black currants (Whelan, 2009).

Assumptions, Limitations, and Delimitations

Assumptions

Assumptions are statements about factors not observable or testable (Neuman, 2011). My first assumption was that physician subjects want to recommend what is in the best interest of their patients. The second assumption was most physicians do not recommend n-3s and this study confirmed this assumption also supported by the literature. The third assumption was the integrity of the physician subjects and the substance of physician conversations supported this assumption. My fourth assumption was that the conducting of interviews in private settings to limit uncontrollable variables (e.g., interruptions) would enhance uniformity, prevent material bias, and ensure confidentiality (Alcadipani & Hodgson, 2009).

Limitations

Two limitations of this study included purposeful sampling of primary care physicians in a limited geography (Kentucky, Indiana, Tennessee). I did not select physician subjects from other specialties because of a lack of relevancy and focus upon cardiovascular preventive medicine. Physicians in a wider geography, for example, on the west coast or east coast of the United States may have different viewpoints of n-3s.

A third limitation was the sample size ($n = 20$), although I did not gather significant new information after the 15th interview and therefore, believe I reached the point of saturation in less than 20 interviews. Saturation is a guiding principle of sample size determination in qualitative studies (Carlsen & Glenton, 2011). Mason (2010) asserted the concept of saturation is elastic and true saturation is contingent upon a

number of variables such as the aims of the study, homogeneity of participants, and skill of the interviewer. The focused aims of this study, similar specialties among physician subjects in a limited geography, and richness of data gathered during interviews support the possibility of achieved sample saturation for this defined population.

Kerr (2010) that explained investigators cannot predict saturation before the study but for practical purposes, investigators need to plan number of subjects. From a literature review, Kerr determined investigators who sought to establish sample size guidelines for qualitative methods of inquiry advocated samples sizes of six to 20 subjects. Similar to Mason (2010), Kerr stated that saturation depended upon heterogeneity of subjects and study objectives. These guidelines support the purposeful sample size for this focused physician decision-criteria marketing study.

Delimitations

Delimitations included the conscious inclusion and exclusion criteria specified in this study and *Informed Consent*. I based purposeful selection upon interest in the study subject, an open perspective regarding diverse opinions, and access. Geographical scope and a willingness to set aside sufficient time without interruptions in a private setting defined acceptable participant access criteria. Considering these delimitations, I could not determine if interviews would have elicited different data if the physician participants did not have an interest in the topic, practiced in states other than Kentucky, Indiana, and Tennessee, or who did not agree to participate in this study.

Significance of the Study

Reduction of Gaps

Marketers of n-3s may benefit from the research findings of this study to improve understanding of how physicians think regarding prescribing or recommending decisions. The ladder of inference posits individuals do not test self-generating beliefs to validate truth (Argyris, 1976). For example, individuals believe own beliefs are the truth, and the truths they believe are the obvious truths. Individuals also believe they base beliefs and conclusions upon real data (Argyris, 1976). The next ladder is the data individuals select to believe to formulate truth is, in fact, real data (Argyris, 1976). In this study, I examined the steps in the ladder of inference relevant to prescribing or recommending decisions; these important study outcomes may reveal strategic business opportunities for marketers of n-3 dietary supplements.

One unintended, but relevant, theme that emerged from this study was the physician participants' unanimous and unsolicited opinions regarding the inadequacy of dietary supplement training in medical schools. This theme reinforces the findings of Adams, Kohlmeier, and Zeisel (2010). Based upon ProQuest multiple database searches, few studies have been published regarding this subject.

Implications for Social Change

Validating prospective business (marketing) and societal benefits were central intentions of this study. In a university IRB-approved pilot interview with a physician, J. Lach (personal communication, November 17, 2011), Lach confirmed the prevalence of cardiovascular disease in his practice and in the general U.S. population. Lach expounded

upon the possible social benefits of a preventive cardiovascular disease product like Lovaza. The data from the pilot interview, therefore, confirmed the prospective social change benefits of this study. Contemplating the effects of physicians' more frequent prescribing and recommending n-3s (behavioral change), physicians who participated in this study confirmed the possibility of substantial societal benefits resulting from reduced cardiovascular disease, providing the positive outcomes of some n-3 studies were true and the negative outcomes of other n-3 studies were not true.

Study Prospects for Improving Society

Change occurs when a research study affects society. In this case, the marketing of n-3 supplements, medicine, and science intersect each other with possibly different values (Matheson, 2008). Matheson expounded how business profits motivate pharmaceutical marketers, good health motivates physicians, and the truth motivates researchers. So determining this study's prospects for improving society requires objectivity with respect to n-3 safety and efficacy as well as a fair appraisal of the impact of effective marketing on society. The outcomes from this study may drive improved communication and symmetry between physicians and patients regarding accountability for preventive health. Physicians may more effectively collaborate with their patients to accomplish requisite n-3 dietary changes. All of this may be positive for society, providing n-3s deliver the preventive cardiovascular disease benefits claimed in many but not all clinical studies.

The societal implications for this study follow a sequential chain. First, marketers' improved understanding of physician inference ladders may enable more effective

communication between n-3 marketers and physicians regarding the possible preventive cardiovascular disease value of n-3 dietary supplementation. Second, physicians' assumptions and conclusions based upon credible, observable data may lead to a more educated cognitive framework regarding n-3s. Third, physicians' experiences may reinforce behavioral change. The change in physician subjects' attitudes and behaviors may expand preventive medicine practice.

When published, study results may expand societal benefits in a wider, national geography. Additionally, study findings may influence the population of primary care and specialist physicians to recommend n-3s to their patients as preventive medicine. America's cardiovascular disease epidemiology may decrease along with the concomitant health interventional treatment costs.

A Review of the Professional and Academic Literature

This section includes six related literature review areas. First, I identify and describe CAM as the nondrug classification system including n-3s. Next, a portion of the literature review supports the efficacy, safety of the correct n-3s, and n-3 daily dosages as dietary supplements although another portion of the literature review raises questions regarding the safety and efficacy of n-3s. In the subsequent three sections, I cite literature to support the knowledge deficiency and need for physician education as well as a framework for understanding physicians' recommending and prescribing decisions. In the final section, I highlight the importance of the role of the patient and the importance of the physician's achievement of patient conviction and compliance. The literature review encompasses multiple databases and search engines, including ProQuest Central,

ABI/Inform Complete, Academic Search Complete/Premier, Science Direct, Business Source Complete, Google Scholar, and PubMed. Additionally, corporate and trade sources provided leads to scholarly journals. I used search words such as "omega-3," "cardiovascular disease," "eicosopentanoic acid," "docosahexanoic acid," "fish oil," "fish oil contaminants," "dietary supplements," "physician education of dietary supplements," "omega-3 clinical evidence," "omega-3 safety," and "omega-3 efficacy."

Complementary and Alternative Medicine

The Cochrane Collaboration has become an important source of information collection and organization of 396 reviews regarding CAM therapies (Wieland et al., 2011). The Cochrane Collaboration has defined CAM operationally, and Wieland et al. (2011) articulated how the standardized definition has provided an objective, reproducible, and systematic method for defining, revising, and classifying multiple CAM therapies. Wieland et al. described how some medical school officials have integrated CAM therapies into medical school curricula, in addition to randomized controlled trials (RCTs) and systematic reviews. Despite increased mainstream openness to CAM therapies, practitioners, researchers, and consumers concede certain therapies remain outside the mainstream medical model such as CAM therapies. For example, according to Wieland et al., medical professionals agreed acupuncture is a CAM classification but disagreed about other CAM classifications, such as vitamin supplements. To reduce ambiguity, enhance understanding of the field, guide research, and augment the safe use of CAM therapies, Wieland et al. described how a theoretical

definition of CAM evolved into a more important and pragmatic standardized operational CAM definition.

In this classification process, Wieland et al. (2011) first considered theories of disease and whether or not the historic notion of the subject therapy was considered CAM or conventional. Second, the researchers excluded CAM classifications from entities currently accepted by the medical community, including insurance payers and the FDA. Third, the researchers considered who administered the therapies; they were more likely to classify therapies as CAM if the patient self-administered the therapy or if non-medical practitioners administered the therapy. Interestingly, Wieland et al. did not include efficacy evidence because they noted the presence of too many therapies not currently accepted as efficacious (e.g., chemotherapy), or noted the lack of convincing evidence of efficacy.

Wieland et al. (2011) considered information obtained from the US National Library of Medicine's PubMed database, including the Medical Subject Headings definition of complementary therapies and the complementary medicine-subset search strategy. From the review and decision process described above, Wieland et al. identified 51 groups of CAM therapies used for treating or preventing disease. Wieland et al. gave preference to CAM therapies in their operational definitions to therapies previously subjected to RCTs. Wieland et al. noted they would expand their operational CAM definitions over time as additional clinical research is completed.

The Cochrane CAM field listed more than 200 CAM therapies. Regarding n-3s, the physician researchers included fish oil (n-3s) as one classification, but also included

DHA and EPA as separate classifications. Perhaps the reason for overlap is Wieland et al. (2011) described RCT evidence as an important criterion for inclusion. See Appendix A for the CAM therapy list.

To assess physician acceptance of CAM, Johnson, Priestley, Porter, and Petrillo (2010) conducted an online survey to members of a professional health educator listserv (n = 501). The researchers' purpose of their study was to examine health educators' attitudes regarding CAM while examining the educators' use of CAM therapies, presumably to confirm expressed attitudes by the educators. The study results indicated educators have positive attitudes toward CAM in general.

Ninety percent of respondents used at least one CAM therapy in the previous 12 months (Johnson, Priestley, Porter, & Petrillo, 2010). On a 5-point scale, a score of 1 indicated the respondents strongly agreed, whereas a score of 5 meant the respondents strongly disagreed. The response scores of men and women respondents to the statement "CAM should be included in professional health education preparation curriculum" were 2.2 and 1.87, respectively. To the statement "CAM is a threat to public health," the male respondent mean score was 3.93 and the female mean score was 4.23. The researchers noted a physician interest in CAM and CAM use by physicians was increasing in the United States.

Omega-3 Cardiovascular Efficacy and Safety

In this section, I provide evidence to support, as well as refute, the efficacy and safety of n-3s. Harvard University and University of Western Australia authors Mozaffarian and Wu (2012) posited clinical evidence indicates EPA and DHA possess

collective and complementary cardiovascular benefits for humans. Some studies noted by Mozaffarian and Wu suggested favorable cardiac diastolic filling (facilitated cardiac blood flow), arterial compliance (arterial wall flexibility), and reduced metrics of inflammation and oxidative stress. Combined EPA + DHA or docosapentanoic (DPA) acid + DHA levels were associated with a lower risk of fatal cardiac events. The authors noted based upon the current evidence, increasing consumption of either DHA or EPA would offer cardiovascular advantages versus little or no consumption.

Reviewing clinical trials including more than 30,000 subjects with cardiovascular or hyperlipidemia history—the Diet and Reinfarcation Trial (DART), Japan EPA Liquid Intervention Study (JELIS), and Gruppo study Italiano per lo Studio della Sopravivenza nell'Infarto Miocardico (GISSI), Vrablik et al. (2009) opined a number of conclusions. First, Vlabik et al. determined uncontrolled diets as independent variables in clinical trials could influence study outcomes, especially in long-term follow up. The investigators opined evidence supported a recommended daily EPA and DHA dietary supplement intake of 500 mg to 1,000 mg.

Vrablik et al. (2009) also opined EPA and DHA could reduce triglyceride levels by 25%-35% and in cases of severe hypertriglyceridemia, by 45%. Vrabik et al. also observed evidence where only DHA increased the levels of good cholesterol HDL. The researchers suggested both EPA and DHA reduce atherosclerosis development, reduce blood pressure slightly (5.8 mmHg for systolic and 3.3 mmHg for diastolic), and at higher doses (>2g/day), reduce systemic inflammation and inhibit platelet aggregation.

In another literature review, De Caterina (2011) recapped the history of n-3s, from obscurity to substantial researcher interest. In the 1960s, Danish investigators reported the Greenland Inuit population showed a low incidence of heart disease. In the first epidemiologic observations of Inuits in Greenland (who regularly consumed a diet consisting of fish, seal, and whale), scientists suspected a nutritional factor was associated with cardiovascular protection. These observations were later confirmed in studies of Northern Canada and Alaska natives who consumed traditional diets as well as high fish-consuming Japanese, Western, and Chinese (De Caterina, 2011) and rural inhabitants Nenet Autonomous Okrug in Russia (Petrenya et al., 2012).

In 25 studies involving 280,000 participants, De Caterina (2011) reported an inverse association between fish consumption and morbidity or mortality from coronary heart disease. De Caterina determined blood levels of n-3 fatty acids correlated inversely with death from cardiovascular causes and total mortality. De Caterina also cited clinical trials with other cardiovascular outcomes including lowered triglycerides, reduced risk of sudden cardiac death, decreased systemic inflammation, slowed buildup of atherosclerotic plaque, and reduced risk of thrombosis and stroke. De Caterina stated the AHA recommended adults eat fatty fish at least twice a week as well as vegetables containing n-3 fatty acids (ALA). De Caterina noted the AHA also recommended coronary heart disease patients consume approximately one gram of EPA and DHA (combined) per day, from oily fish or fish-oil capsules (with physician consultation and advice). The AHA recommended higher daily doses of EPA and DHA (2 - 4 grams) as useful in patients with severe hypertriglyceridemia (> 500 mg of triglycerides per

deciliter) to reduce serum triglyceride levels by 20% to 40%. In this paradox, Catarina explained how one type of desirable fatty substance lowers another undesirable fat in the human body.

In a blood sample experiment, Holub, Wlodek, Rowe, and Piekarski (2009) reported correlative results from living human subjects (n = 2,053). The researchers compared fatty acid ratios between anti-inflammatory, healthy n-3 (EPA and DHA) with the pro-inflammatory n-6 arachidonic acid using the following ratios: n-6/n-3, AA/EPA, AA/DHA, and AA/EPA + DHA. Although correlational analyses indicated inverse relationships between the concentration of n-3s in the serum and each of the four ratios in phospholipids, the researchers concluded the strongest statistically significant inverse relationship was evident between serum n-3s and the n-6/n-3 ratio. These research results support a diet high in n-3s will reduce the level of n-6s in serum phospholipids and support the theory of preferential cell wall acceptance of n-3s over n-6s, thus reducing deleterious health effects of phospholipids too high in n-6 concentrations. In a controlled quantitative experiment consisting of 107 hyperlipidemia patients, Krysiak, Gdula-dymek, and Okopien (2011) also found a diet high in n-3s (EPA 465 mg and DHA 375 mg twice daily) significantly lowered plasma triglycerides ($p < 0.05$).

In another study, Saravanan, Davidson, Schmidt, and Calder (2010) presented evidence of n-3 efficacy in reducing triglycerides and reducing the incidences of heart failure, atherosclerosis, stroke, and systemic inflammation. Regarding inflammation, Saravanan et al. discussed anti-inflammatory mechanisms including n-3 modulating effects on neutrophils, macrophages, T-cells, and dendritic cells. In the presence of

certain pro-inflammatory stimuli (e.g., n-6s) these cells release chemical mediators to increase the inflammatory response. Systemic inflammation of blood vessel walls can lead to cardiovascular disease.

Saravanan et al. (2010) reviewed clinical trials to assess daily EPA/DHA dosage regimens, ranging between 1 gram to 4 grams per day, depending upon triglyceride level acuity and patients' regular dietary consumption of n-3 fatty fish. The authors determined a one-gram daily dosage of EPA and DHA dietary supplements equals an intake of 55 grams of tuna, trout, salmon, or sardines, and 652 grams of cod. To determine adequate intake, Saravanan et al. used the n-3 index. The n-3 index is a relatively new approach to determine the appropriate quantity of n-3s in the body by measuring the amount of EPA and DHA in red blood cells. Saravanan et al. reported an n-3 index of 8% or higher as the guideline for the highest cardiovascular protection whereas an n-3 index of 4% or lower as the least cardiovascular protection.

In another study, Soltan and Gibson (2008) provided information regarding recommended daily intake recommendations for n-3 ingestion and concentrations of n-3s by fish type. The researchers recommended 500 mg/day of DHA/EPA n-3s in healthy adults, 1g/day for patients with coronary heart disease, and 2–4g/day for patients with hypertriglyceridemia. In general, researchers determined that fatty fish provided potent sources of n-3s thereby reducing consumption requirements to achieve daily desired n-3 intake. Unfortunately, several species of popular dietary fish provide poor quantities of n-3s. Poor sources include Atlantic cod, whiting, barramundi, and southern Bluefin tuna. Farmed tuna contained considerably more desirable n-3 fat than wild tuna.

Soltan and Gibson (2008) determined the most potent sources of fish species for n-3s were swordfish and Atlantic salmon. Consumption of only 40g (1.4 ounces) of these species provides 1 gram of n-3s. Conversely, an individual would have to consume approximately 400g (14 ounces) of barramundi or southern Bluefin tuna to ingest 1g of n-3s. The researchers noted the impracticality of ingesting enough popular dietary fish portions to achieve sufficient n-3 levels and emphasized the need for n-3 dietary supplements. Soltan and Gibson also elucidated how some fish contained much arachidonic acid, an undesirable n-6 fatty acid. Fish species with high n-6 content include northern whiting, shrimp, and barramundi. Popular dietary fish with low n-6 content include salmon, red snapper, and southern Bluefin tuna.

Deckelbaum and Torrejon (2012) reported n-3s promote health and prevent disease in a number of human body systems, but the mechanisms of EPA and DHA may be the most remarkable in cardiovascular disease. Cardiovascular benefits result from progressive chain mechanisms improving chemotaxis and other anti-inflammatory responses, reducing oxidative damage and systemic inflammation, reducing atherogenesis, reducing vascular resistance, and lowering blood pressure. However, Deckelbaum and Torrejon noted the inadequacy of cold water fish and other dietary sources to achieve n-3 daily intake recommendations.

As one partial solution, Deckelbaum and Torrejon (2012) recommended genetic modification of soybeans to produce high volumes of stearidonic acid (SDA). In human metabolism, the body synthesizes SDA into EPA. In another study including SDA, Whelan (2009) advocated the therapeutic and health-promoting effects of n-3s from fatty

fish sources and SDA because an n-3 precursor found in many vegetable oils, α-linolenic (ALA), may not provide the same health benefits because of its partial conversion to n-6 and n-9 fatty acids.

Whelan (2009) noted another benefit of investigated fatty acid, SDA, as an alternative source of n-3 because of concerns for fish oil purity. According to Whelan, researchers have determined SDA may have similar biological properties to EPA. SDA sources include soybean oil, black current, and hemp seed oil. In a scientific comparison, Whelan concluded SDA shares many of the same biological effects as EPA, and therefore, may become an important food additive and contribute a significant supply of n-3 dietary supplementation for the Western world.

Based on a meta-analysis of 25 RCTs, Whelan et al. (2012) concluded EPA and DHA dietary intakes, on average, reduced triglyceride levels 27 mmol/L. In their literature review, they found EPA and DHA dietary intake had the most pronounced effects on circulating triglyceride levels at daily doses > 2g/day, but with smaller effects on HDL and LDL cholesterol levels. Dosages ranged from 0.8g to 5.4g/day. Whelan et al. highlighted most studies employed dosages in the 2–4g/day, with the most pronounced effects on triglycerides at doses greater than or equal to 3g/day.

Marik and Varon (2009) reviewed 11 randomized, placebo-controlled studies, including 39,044 patients with histories of recent myocardial infarction, heart failure, implanted cardioverter defibrillator, hypercholesterolemia, and peripheral vascular disease. Average doses of n-3 EPA and DHA ranged from 0.6–3.0g/day. Patient follow-up period ranged from 1.0–3.4 years. Marik and Varon concluded specific EPA/DHA n-3

dietary supplementation reduced the risk of cardiovascular deaths ($p = 0.002$), sudden cardiac death ($p = 0.04$), all-cause mortality ($p = 0.02$), and nonfatal cardiovascular events ($p = 0.02$). Although multiple regression analyses did not demonstrate a dose-response relationship, patients in this study ingested higher average doses than recommended by the 2008 expert panel (Harris et al. 2009). The authors recommended n-3 dietary supplements as a practice of secondary cardiovascular event prevention.

N-3 fatty acids may reduce blood pressure and pulse rate according to the results of a meta-analysis by Hoy and Keating (2009). A mean systolic/diastolic BP reduction of 2.3/1.5 mm/Hg occurred with a mean n-3 dosage of 4100 mg/day. In subgroups, Hoy and Keating reported more meaningful blood pressure reduction in older subjects (age >45 years) versus younger subjects. Additionally, Hoy and Keating determined hypertensive subjects experienced more blood pressure reduction than did normotensive patients. Hoy and Keating also determined n-3s reduced pulse rate. Mean heart rate was significantly ($p = 0.002$ vs. placebo) reduced by 1.6 beats/minute in subjects who consumed a median n-3 dosage of 3500 mg/day. In subgroup analysis, Hoy and Keating discovered a significant ($p < 0.001$) reduction of 2.5 beats/minute in subjects with mean heart rates of ≥69 beats/minute at baseline, but no significant change in subjects with mean heart rates of <69 beats/minute at baseline.

Regarding recommended n-3 dosages, Hoy and Keating (2009) opined n-3 dosages for the secondary prevention in patients with a history of myocardial infarction is 1000 mg/day. In patients with hypertriglyceridaemia, Hoy and Keating recommended a dosage regimen of 2,000 mg/day – 4,000 mg/day depending upon patient response. The

researchers noted patients might choose to take n-3 supplements with food to avoid gastrointestinal disturbances. This analysis demonstrated sufficient n-3 dosages may provide clinically significant reductions in serum triglyceride levels, blood pressure reduction in patients with untreated high blood pressure, and heart rate reduction, irrespective of sex or age.

Somewhat confirmatory, Cabo, Alonso, and Mata (2012) reported some studies indicated n-3 consumption reduces systolic blood pressure. However, Cabo et al. noted study results were not consistent. Cabo et al. recommended n-3 supplementation as beneficial for mildly hypertensive patients, preferring dietary changes before starting drug therapy.

As a corollary to cardiovascular disease, Grenon, Hughes-Fulford, Rapp, and Conte (2011) cited population studies indicating peripheral artery disease (PAD) affects more than 12% of people over 65 and 20% over 75. Grenon et al. explained PAD treatments cost more annually than coronary artery disease or cerebrovascular disease. PAD also includes development of thromboses resulting in possible emboli.

Explaining the root causes of PAD, Grenon et al. (2011) confirmed U.S. daily dietary intake of 1.6g of ALA, but noted ALA's inferior desirable biological activity to EPA and DHA. Grenon et al. also compared the average dietary intake of ALA (1.6g) to the average dietary intake of 14.8g/day of n-6 linoleic acid. They listed sources of n-6 fatty acids as corn oil, soybean oil, safflower oil, and sunflower oil. Sources of n-6 arachidonic acid include poultry and meats. Conversely, sources of ALA include flaxseed

oil, canola oil, and soybean oil but soybean oil contains more LA than ALA. Grenon et al. listed only oily fish and fish oil capsules as viable sources of EPA and DHA.

Grenon et al. (2011) explained the differences in end-mediators resulting from consuming n-3s versus n-6s in the diet. Consuming n-6 produces end-mediators to promote systemic inflammation, including lipoxins, thromboxanes, prostacyclins, and leukotrienes. Conversely, n-3s produce resolvins and protectins, substances active to turn off inflammation. Tartibian, Maleki, and Abbasi (2010) explained how n-3s also alter cyclo-oxygenase and lipoxygenase pathways to reduce inflammation. Somewhat evidentiary, the Tartibian et al. study demonstrated how n-3 consumption during intense wrestling training improved pulmonary function of wrestler athletes. Grenon et al. also reported one fish-oil-enriched meal improved flow-mediated brachial artery vasodilation (FAD). Improved FAD for PAD patients may lower systemic inflammation and reduce progressive atherosclerosis, improving circulation and abating the risk of PAD.

The circulatory effects resulting from ALA dietary consumption evolve from complex chemical mediator synthesis mechanisms. Discussing dietary plant oils as sources of ALA and n-3s,Vrablik, Prusikova, Snejdrlova, and Zlatohlavek (2009) explained of the essential n-3s, ALA, which is present in plant oils such as walnuts, soybeans, and flaxseeds, only 5% of ALA is converted into EPA and DHA in the body. Most of the ALA converts to n-6 arachidonic acid, thereby adding to the excessive and potentially harmful levels of arachidonic acid already prevalent in the American diet. This conversion process adds understanding of another way (in addition to red meat consumption) n-6s accumulate in the body.

As possible contradictory evidence to the dietary effects of ALA, Kris-Etherton, Hu, Ros, and Sabaté (2008) advocated the possible health value of ALA in nuts. Kris-Etherton et al. also discussed how after ingestion, the body converts some ALA to EPA. Pooling results from four U.S. epidemiological clinical studies, Kris-Etherton et al. evaluated cardiovascular health effects from the consumption of different tree nuts and peanuts, dietary sources of ALA and other cardio-protective nutrients. The study compilation indicated individuals who consumed nuts five or more times per week reduced risk of fatal coronary heart disease by 39% and nonfatal myocardial infarction by 32%. Additionally, men who consumed nuts two times per week had a 47% reduction in sudden cardiac death. Subjects who consumed peanuts twice per week had a lower incidence of coronary heart disease by 34%.

Kris-Etherton et al. (2008) described the ingredients and mechanisms by which nuts exert these health benefits. The nut mechanisms reduce oxidation, reduce systemic inflammation, and reduce vascular reactivity. Nut ingredients that reduce oxidation include tocopherols, phenoloic antioxidants, melatonin from walnuts, mononsaturated fats, and PUFAs. Nut ingredients that reduce inflammation (as measured by a reduction in circulating C-reactive protein [CRP] levels) include ALA, metabolized in the body to PUFA n-3s. Nut ingredients responsible for increased vascular reactivity (vasodilation, reduced cellular adhesion to blood vessel walls, reduced atherosclerosis) include l-arginine, ALA (to n-3), and other antioxidant nutrients.

Kris-Etherton et al. (2008) noted the predominant study of walnuts as potent sources of these desirable active ingredients. Kris-Etherton et al. cited the American

College of Cardiology prediction by 2050 the American incidence of cardiovascular disease will double. They advocated an overall diet high in fruits, vegetables, nuts, whole grains, legumes, low-fat dairy products, and lean protein.

In another study, Tovar et al. (2012) advocated the modulating effects of a healthy diet including n-3s in individuals with cardio-metabolic diseases (CMD) and metabolic syndrome (MetS). Administering a healthy diet with daily intakes of multiple function foods including n-3s (subject daily dosages were 2.4g for women and 3.0g for men), Tovar et al. demonstrated statistically significant CMD and MetS risk-reduction health benefits. In a crossover design study with treatment and washout periods each lasting 4 weeks, subjects (n = 44) between the ages 50 to 73 were randomly assigned to either a control diet (CD) or active diet (AD). Subjects maintained their habitual diets during the CD arm. The AD included a specified menu including (a) items rich in antioxidants; (b) n-3s; (c) probiotics (*Lactobacillus* strain) and prebiotics, including intact barley kernels, whole kernel rye flower, and isolated barley fiber; (d) low glycemic foods, such as high fiber bread, whey protein, and vinegar; and (e) soybean products and margarine enriched in stanol esters and dry almonds.

Tovar et al. (2012) determined statistically significant CMD and MetS risk-reducing effects from the AD arm but not the CD arm. The AD arm benefits included: (a) 8% reduction in systolic BP, (b) reduced high sensitivity C-reactive protein (hs-CRP) scores by 29%, indicating reduced vascular inflammation, (c) lower Framingham Study algorithm cardiovascular risk scores by 30%, and (d) lower Reynolds cardiovascular risk scores by 35%. AD arm benefits also included: (a) reduction in triglycerides by 19%, (b)

reduction in LDL by 34%, (c) reduction in HDL by 10%, (d) reduction in the LDL/HDL ratio by 27%, and (e) reduction in the ApoB/ApoA-1 ratio by 10%. The ApoB/ApoA-1 ratio measures apolipoproteins, which when combined with LDL/HDL cholesterol ratios indicate risk of MetS.

Tovar et al. (2012) noted the satiating effects of the AD, which allowed ingestion of some animal meat and how the AD was more effective than the Mediterranean diet, the Nordic diet, and the vegetarian diet in its reduction of systemic inflammation and cardiovascular risk. Although not an intended study outcome, the researchers posited the weight loss drop in the AD group probably resulted from satiety associated with the diet higher in protein content. Tovar et al. stated the drop in systolic BP probably resulted from the high dietary supply of long-chain n-3s. Although the researchers in this study did not focus singularly upon n-3 efficacy, the Tovar et al. provided some evidence of the possible contributory and potentiating effects of n-3s upon good cardiovascular health when combined with other healthy dietary initiatives (see Appendix B).

In another study of n-3s with other dietary supplements, (Radler, et al., 2011) demonstrated health benefits of n-3 ingestion combined with polyphenols and L-carnitine in MetS subjects ($n = 22$). After 12 weeks of therapy, subjects experienced a free fatty acid serum reduction of - 29% and serum triglyceride reduction of - 24% (each $p < 0.05$). Although the findings were statistically significant, one limitation of this trial was the combination therapy.

From a global perspective, clinical research outcomes have enhanced international interest in n-3s (Ginsberg & Toal, 2009). Ginsberg and Toal reported consumer concerns

regarding negative methyl-mercury purity messages and therefore developed a risk/benefit summary for consumption by fish species. Farmed salmon, herring, and trout species had the highest benefit/risk ratio. Other species had a small net benefit or net risk rating (e.g., flounder, canned light or white tuna, halibut) but swordfish and shark rated high risk/low benefit. A logical conclusion is concentrated EPA/DHA purified fish oil supplements may provide n-3 health benefits while obviating methyl-mercury consumption risks associated with commercial fish food species. According to De Caterina (2011), the AHA advised caution with respect to fish contaminants but acknowledges some species are low in methyl-mercury, noting fish oil supplements are free of methyl-mercury.

The following studies also provide some evidence to question the safety and efficacy of n-3s. In a meta-analysis of clinical trials including 33,429 subjects with cardiovascular disease, Chen et al. (2011) determined no significant differences in lowered epidemiology of sudden cardiac death, cardiac death, and all-cause mortality. One limitation of the Chen et al. analysis was trial heterogeneity including n-3 dosage, baseline disease severity, and follow-up duration. One important feature to this study is 46% of subjects were receiving concomitant statin therapy to lower cholesterol and triglycerides.

Regarding SDA as a source of n-3s, Whelan, Gouffon, and Zhao (2012) questioned the suitability of genetically altered SDA as a replacement for DHA/EPA from fish sources. Whelan et al. (2012) noted the challenge of a sustainable fatty fish supply to provide the world population ample n-3 dietary supplementation. Whelan et al.

noted previous researchers who advocated genetically altered soybean oil modified to produce SDA concentrations of at least 30%, as a suitable replacement for EPA from fish sources at a ratio of 3.7 grams of SDA to one gram of EPA. In a retrospective review of three human clinical trials comparing SDA with EPA for clinical effects in lower triglycerides as well as LDL and HDL cholesterol levels, Whelan et al. determined SDA was not effective in lowering triglycerides, HDL, or LDL levels.

In a presentation of evidence after evaluating several epidemiological studies spanning 15 years, Borghi and Pareo (2012) raised skepticism regarding the efficacy of n-3s in reducing ventricular arrhythmias. The investigators acknowledged the role of n-3s in moderating atrial fibrillation. Borghi and Pareo opined n-3s may not reduce the incidence of cardiac mortality and sudden death in ventricular arrhythmic patients.

Raising skepticism of n-e efficacy in a specific patient group, Bosch et al. (2012) studied 12,536 patients who were at high risk for cardiovascular events. Study subjects received at least 900 mg ethyl ester n-3s or placebo daily and the investigators followed this group for a median period of 6.2 years. This group of high-risk patients included those with glucose metabolism impairment: impaired fasting glucose, impaired glucose tolerance, or diabetes. Bosch et al. concluded n-3s had no effect on cardiovascular outcomes in this group of high-risk patients.

In a literature review of n-3 clinical trials, Vlablik, Prusikova, Snejdrlova, and Zlatohlavek (2009) raised the possibility n-3 dietary supplementation may raise undesirable low-density lipoprotein (LDL) cholesterol levels when used in high doses for patients with hypertriglyceridemia. Vlabik et al. explained EPA is the specific n-3

correlated with higher LDL blood levels. Vlabik et al. noted the effects of EPA on LDL levels may be mitigated by DHA because investigators have demonstrated DHA increases desirable high-density lipoproteins (HDL). Vlabik et al. explained DHA changes the sub-fraction distribution of LDL particles so the particles are less sticky and therefore less likely to contribute to atherosclerosis. Therefore, for patients taking high doses the inclusion of sufficient DHA in n-3 formulas with EPA may prevent a rise in LDL or at least prevent deleterious health effects associated with higher LDL.

In a multicenter, double-blind, randomized, placebo-control trial of 4,837 patients with previous myocardial infarction incidents, Kromhout, Giltay, and Geleijnse (2010) determined low dose n-3 dietary supplemenation (226 mg EPA and 150 mg DHA) did not reduce fatal or nonfatal cardiovascular events. Subjects consumed margarines with EPA/DHA, ALA, or placebo identical appearances and investigators monitored cardiac events for up to 40 months. A total of 13.9% of all patients experienced major cardiovascular events and the rate of events in the EPA/DHA group was 46 per 1,000 compared to the rate of cardiovascular events for placebo or ALA of 45.7 per 1,000.

In a study of 834 men with prostate cancer, Brasky et al. (2013) linked high n-3 blood levels to increased prostate cancer (i.e., 44% increase in low-grade prostate cancer risk and 71% increase in high-grade prostate cancer risk). Brasky et al. also correlated higher blood levels of linoleic acid (n-6s) to a lower incidence of prostate cancer. The authors opined n-3 fatty acids are involved in prostate carcinogenesis. Other investigators attribute prostate carcinogenesis to environmental toxins including pesticides and trace

minerals (Mullins & Loeb, 2012). Unpurified fish oils may contain one or more of these toxins including methylmercury (Ginsberg & Toal, 2009).

In an objective to assess the role of n-3s on major cardiovascular outcomes, Rizos, Ntzani, Bika, Kostapanos, and Elisaf (2012) reviewed 20 studies including 68,680 patients reporting 7,044 deaths, 3,993 cardiac deaths, 1,150 sudden deaths, 1,837 myocardial infarctions (MI), and 1,490 strokes. Rizos determined no statistically significant correlation between n-3 supplementation and lower risk of all-cause mortality, cardiac death, sudden death, MI, or stroke. The investigators concluded the published randomized evidence does not support universally statistically significant reductions in cardiovascular outcomes in different patient populations. The studies in this section may inform n-3 marketers of important, contradictory n-3 viewpoints and evidence.

Applicable Decision Criteria and Theory

In the following sections, I describe several decision variables applicable to physician prescribing decisions. The multiattribute utility (MAU) decision model is appropriate to facilitate understanding complex, prescribing decisions. The MAU model constructs utilities and consequences of individual decisions. Weiss et al. (2010) proposed a modified MAU decision model including the variable momentary salience to explain violations of individual policies. Weiss et al. simplified the MAU decision hierarchy for pragmatic purposes to differentiate between every day, little decisions, and infrequent, big decisions.

Momentary salience is primarily an emotional influencer including the influences of personal mood and environment. The modified MAU decision model is important in

the context of this ladder of inference study, because physicians evaluate complex utilities and consequences expected from prescribing decisions but at the same, can be influenced by momentary salience factors. This modified MAU theory provides a corollary framework to ladder of inference theory to facilitate the organization and understanding of physicians' logic, beliefs, and desires triggering their n-3 recommending/prescribing behavior.

In business marketing settings, rather than the psychological construct MAU, marketing vernacular uses *customer needs*. Customer needs apply to both physicians and patients, because patients are the end-consumers; although the focus of this study is upon physician–customer needs. Modified MAU and ladder of inference theories, used together when analyzing and interpreting study data may augment trustworthiness to study outcomes. Using both theories simultaneously may facilitate the translation of empirical, psychological study findings to pragmatic, business purposes of fulfilling customer needs.

Customer Needs and Ladder of Inference

A justificatory starting point for inference ladder application and understanding defines basic customer needs. Montoya, Netzer, and Jedidi (2010) revealed physicians respond to competent pharmaceutical detailing of efficacy and safety features as well as receiving drug samples the physicians can trial with patients. Physician detailing and drug sampling support physician needs, evidentiary by the 2005 United States pharmaceutical industry marketing spending the majority of approximately $18 billion on physician detailing and drug sampling (Montoya et al., 2010). In a longitudinal analysis

(24 months) following a firm's launch of a post-menopausal drug, Montoya et al. evaluated the effectiveness of sampling and detailing on driving prescriptions and discovered company waste through excessive sampling, excessive detailing, and incorrect physician targeting. Montoya et al. concluded both detailing and sampling have long-term influence on physicians' prescriptions; detailing is particularly effective as an acquisition tool whereas sampling is mostly effective as a retention tool.

In addition, Montoya et al. (2010) determined sampling had a stronger short-term effect than detailing, but detailing had a stronger long-term effect. The researchers also demonstrated how ignoring physician buying behavior dynamics and not evaluating marketing activity effectiveness could lead to suboptimal resource allocation. Detailing and sampling activities fulfill customer needs as Montoya et al. demonstrated by physician prescribing behavior frequency (i.e., inactive, infrequent, and frequent prescribing). These physician-customer satisfaction elements apply to physician ladder of inference analysis. Information from pharmaceutical detailing is intriguing, because physician acceptance of information perceived as complete and accurate is a similar construct to ladder of inference data observation and selection. Subject relevant, n-3 dietary supplement cardiovascular efficacy, safety, and differential quality attributes may influence physicians to recommend n-3s.

Montoya et al. (2010) did not differentiate between relational and transactional decision influencers from detailing. These influencers may be obvious or hidden. To identify hidden influencers, Gofman, Moskowitz, and Mets (2010) presented rule developing experimentation (RDE), an adapted conjoint analysis model. RDE is a

systematic approach to random experimentation of product feature or promotional messages mixes. Using RDE, researchers determine customer needs and preferences by eliciting customer responses to prototypes. Researchers develop silos of varied and important product or message elements and present combinations likely to appeal to customers. The underlying RDE conceptual framework applied to this doctoral study to develop deep inquiry interview questions and drive clear understanding of customer needs using follow-up e-mails for member checking of transcript content and theme development among the 20-subject physicians.

Similar to the hidden customer needs discoverable through RDE (Gofman et al., 2010), Bassi (2007) used latent class (LC) analysis to determine which physicians were most receptive to pharmaceutical representative sales calls. Bassi used LC analysis to measure the latent importance of seven criteria to 487 Italian practitioners. The seven criteria included: (a) attention of industry keeping physicians up-to-date, (b) frequency and dependability of pharmaceutical representative visits, (c) helpfulness to physicians with diagnostic and therapeutic problems, (d) respect for physician's experience and their suggestions, (e) knowledge and professionalism of pharmaceutical representatives, (f) industry current events and activities information, and (g) quality of global promotions and information provisions. Using LC factor analysis, Bassi identified, post hoc, which segments of practitioners were most receptive to sales efforts of pharmaceutical representatives.

In a study that the authors designed to evaluate physicians' prescribing decision criteria, researchers Huisman-Baron, van der Veen, Jansen, van Roon, and Brouwers

(2011) posited elderly patients are at increased risk for adverse drug reactions because of physiological changes (e.g., reduced renal or liver function), multiple morbidities, and polypharmacy. The researchers listed the following as primary drug criteria that physicians typically use in drug selection: effectiveness, safety, clinical experience, and convenience. Huisman-Baron et al.'s primary study purpose was to determine the criteria set for optimal drug selection in frail, elderly patients. From a list of 31 questionnaire criteria presented to a panel of 32 physicians who treat geriatric patients as well as 26 pharmacists (n = 58), the group consented upon 23 criteria divided among four categories: effectiveness, safety, experience, and convenience. A criterion of particular relevance to this doctoral study, which included 23 criteria, was the number of doses needed to treat, which Huisman-Baron et al. stated was especially important with preventive medicine, dosage frequency, and cardiovascular adverse events. Through study outcomes, investigators confirmed and explicated prescribing decision criteria and added important considerations for elderly patient formularies.

In a relevant quantitative study (n = 135), Tichelaar et al. (2010) purposed to correlate which factors determined drug choices by medical faculty (generalists and specialists) and final-year medical students, and specifically the impact of the teachers' favored drugs upon the students' choices. As a basis for the study, the researchers noted practicing physicians reach their prescribing decisions heuristically, and therefore, may not be aware of their own drug choice logic or value judgments. Tichelaar et al. noted unlike diagnostic reasoning, which is well documented in the literature, little is known

about therapeutic reasoning (i.e., the decision process physicians use to make treatment choices).

Tichelaar et al. (2010) presented the respondents with six case studies and asked them to rank 14 factors influencing their prescribing decisions. In general, the medical students prescribed similar drugs to general practitioners and ranked examples from teachers as higher influencers. Clinical specialists prescribed a broader range and more potent drug products than generalists or medical students. Generalists and specialists placed more emphasis upon the following practice-related and drug-related factors: own clinical experience, patient convenience, and compliance of the patient (practice related), drug effectiveness, scientific literature, and information from the pharmaceutical industry (drug related). Other decision influencers included easy administration of the drug, side effects, drug costs, therapeutic spectrum, standard treatment guidelines, patient case-studies presented by professors, opinions of colleagues, education, and postgraduate education. Tichelaar et al. concluded medical curricula should include more therapeutic reasoning and medical school professors should present medical students with more clinical problems to add meaning and understanding to the prescribing logic of students.

In a 7-point, Likert scale mail survey to 201 general practitioners and 513 medical students (n = 714), Godin, Beaulieu, Touchette, Lambert, and Dodin (2007) determined to identify those factors leading to physicians' recommending CAM treatments to their patients. Godin et al. measured eight variables as behavioral determinants. Intention was defined by subcomponents: (a) attitude (advantages and disadvantages of CAM treatments), (b) behavioral beliefs, (c) subjective norm, (d) normative beliefs, (e)

perception of control (including knowledge of CAM treatment and reimbursement for treatment), and (f) control beliefs. Attitude referred to a person's overall evaluation of behavior, also measured indirectly by behavioral beliefs. Subjective norm measured the social pressure from others to perform, whereas normative beliefs measured approval perceptions from others resulting from one's behavior. Perception of control was the control extent one perceives to have over self-behavior, and control beliefs pertained to the perceived difficulty or barriers to performing the behavior.

Seventh, variable moral norm measured the intensity of an individual's personal feelings of obligation toward performing the behavior. Eighth and last, descriptive norm measured the individual's perception of the prevalence of behavior among peers. Based on the results of the multivariate analysis of variance (MANOVA) analyses performed in the study, the requisite to CAM prescribing, investigators prioritized the perceptions of the physician and medical students as follows: (a) low risk to health, (b) CAM treatment effectiveness, and (c) absence of conventional treatment alternative. Subjects with positive intentions to recommend CAM treatments also indicated the importance of involving the patient and associations with open-mindedness, contributions to improved health, and a strong therapeutic alliance.

In a relevant retrospective study to determine whether pharmaceutical advertising exerted undue influence on physician prescribing behavior, Joyce, Carrera, Goldman, and Sood (2011) compared narrow versus broad prescribing of drug products in 10 therapeutic classes. The researchers also compared brand and generic prescribing

tendencies among physicians. They measured patient-level outcomes, including medication adherence, therapeutic switching, and out-of-pocket drug costs.

As a measurement instrument, the researchers used the medical possession ratio for medication adherence, defined as the number of days of medication held by the patients over the 6-month period following the physician's initial prescription. Joyce et al. (2011) concluded physicians prescribed broadly in 10 therapeutic categories, choosing generics and brands. In eight out of 10 therapeutic classes, physicians prescribed at least three different drugs. Joyce et al. also noted the physicians regarded pharmaceutical representative detailing as an important source of information. The pharmaceutical representatives' drug sampling also provided greater flexibility for low-income patients as well as clinical experience for physicians.

With respect to drug cost as a physician need, in a study to determine the influence of managed care about physician prescribing habits, Rice (2009) measured the breadth of physician prescribing of 13 drugs during 1997–2000. Also measured was whether physicians in HMOs tended to prescribe the same drug for the same medical condition. Rice determined physicians in HMOs are less diverse in their prescribing choices than choices by other physicians. Rice also determined HMO physicians were more price-sensitive and therefore, more likely to use generic substitutes. Rice concluded HMOs have a modest influence on physicians' prescribing of generic drugs.

Rising healthcare costs drove investigative interest to determine attitudes and factors influencing physicians' prescribing in Greece and Cyprus (Theodorou et al., 2009). In both countries, physicians regarded the National Medicines Organization,

similar to the FDA in the United States, as the most important source of information regarding adverse drug reactions and scientific journals the most important source regarding new drugs. Physicians ranked efficacy as the number one criterion for drug selection justified by publications in medical journals. Regarding adverse drug reactions and new drug information, physicians ranked pharmaceutical representatives as the third most important source of information. Even though Theodorou et al. (2009) reported physician attitudes toward drug therapy, these findings may also define the influences placed upon physicians in their decision-making processes for CAM and n-3 therapies.

Computer-assisted prescribing is another potential influencer of physician prescribing and fulfills a need for information organization and instantaneous access to information. Noting the high volume of prescriptions written and resultant inevitability of some poor outcomes, in a review of two research articles covering 29 trials, Maxwell (2010) presented modest evidence for computer-assisted prescribing. Maxwell noted benefits of computer-assistance to aid physicians with treatment standards, drug interactions, side effects, dosages, lifestyle change recommendations, and even restrictive formularies. In one trial of dyslipidemia patients, the collaborative system improved cholesterol levels slightly over a 1-year period, but the regimen did not include n-3 dietary supplements. The findings in this section provide important background for planning discovery of n-3 recommendation criteria by physicians. Study outcomes may also influence n-3 marketing plans.

Dietary Supplement Physician Education

In a survey, investigators explored physicians' beliefs, attitudes, intentions, knowledge, and behaviors regarding CAM. Milden and Stokols (2004) presented results from 196 board-certified physicians of varying specialties who practiced medicine in California. The findings revealed only 20% of surveyed physicians received some sort of CAM training in medical school. Sixty-one percent of physicians did not regard personal CAM efficacy and safety knowledge as adequate, and 81% of surveyed physicians stated they wanted more CAM education. Milden et al. asserted physicians are crucial in influencing patients' use and beliefs about CAM. These findings raise important issues with respect to physicians' medical education and patient care.

Kemper et al. (2003) assessed knowledge in herbs and dietary supplements (H/DS) in a survey (n = 537) of 111 medical doctors, advanced practice nurses, pharmacists, and dieticians. The e-mailed survey was distributed to in-training (16%) and practicing clinicians (84%) at Harvard Medical School, Children's Hospital, Dana Farber Cancer Institute, Boston Combined Pediatric Residency Program, Massachusetts College of Pharmacy and Health Sciences, Brigham and Women's Hospital, Massachusetts General Hospital, and the Veterans Administration. An important subject inclusion criterion was previous H/DS training. Of the specialists, registered dieticians scored the most correct (60%) on the 10-question survey.

Two important findings of the Kemper et al. (2003) survey were physicians' average score was 9.2 (out of 20) on the H/DS knowledge test and physicians scored 3.0 out of 10 on H/DS confidence questions (i.e., confident to discuss H/DS with patients).

The researchers noted the risks of H/DS and the importance for clinicians to discuss H/DS with patients as routine healthcare practice. Kemper et al. expressed the concern consumers/patients would turn to unqualified store clerks, websites, or popular magazines or books for clinical advice if healthcare professionals were silent.

Physician-authors Ashar and Rowland-Seymour (2008) provided evidence of prevalent consumer use of dietary supplements (20% of the population) to maintain or promote health, spending more than $23 billion annually. Notwithstanding this abundant use, the authors posited that patients and physicians are often unaware of limited government dietary supplement regulation as well as potential risks. Ashar and Rowland-Seymour observed the lack of physician knowledge about dietary supplements potentially strains the doctor–patient relationship. They presented a 6-step approach for physicians to use for competent patient advising. The six steps include (a) inquiring about supplement use, (b) evaluation of the supplement, (c) discussion of DS regulatory issues, (d) discussion of available safety and efficacy data, (e) comparison of the risks and benefits of optional conventional therapies, and (f) monitoring for adverse events and therapeutic responses. Ashar and Rowland-Seymour recommended physicians should enhance their own DS knowledge, a theme consistent with this research project.

In a quantitative study consisting of data from 165 completed physician surveys, Silverstein and Spiegel (2001) posed three primary research questions. The researchers first determined most physicians asked their patients about the use of CAM treatments. Second, physicians did not routinely check references to determine safe usage. Third, Silverstein and Spiegel reported surveyed physicians had insufficient knowledge of CAM

treatments, correctly answering an average of 1.39 out of 10 CAM safety questions. Despite these results, the researchers opined the medical community is increasing its awareness of CAM treatments—benefits and risks.

In a multicenter, online educational intervention program to 335 physicians in 15 internal medicine residency programs, Ashar et al. (2008) conducted an objective assessment of physician DS knowledge. In a pretest, the researchers measured baseline knowledge of commonly used dietary supplements. Despite medical school education and training curricula, baseline knowledge of dietary supplements was low (pretest score $\mu = 59.7\%$). Ashar et al. reported low scores in response to questions regarding safety and drug-supplement interactions. Regarding efficacy, only 36% knew fish oil lowered triglyceride blood levels. They concluded the residents' knowledge of dietary supplements was poor, but an online didactic education module could improve physicians' knowledge and potentially enhance patient–physician communication regarding DS usage.

Legare et al. (2011) noted the role of continuing professional development (CPD) is the primary process physician generalists and specialists use to stay current and improve knowledge and skills requisite for patient care optimization. They developed a global instrument to assess the value of CPD activities on clinical practice. Legare et al. verified the acceptability and value of CPD instruments, what features needed revision, and what CPD instrument content needed deletion or addition. Immediately following completion of CPD and 2 weeks later, session participants completed the assessment tool to rate aspects of the CPD program. Two overriding principles promulgated by promoters

of the knowledge to action process (KTA) for healthcare professionals guided determination of program success: the knowledge creation cycle and the action cycle.

In another study assessing doctor–patient communication of DS, Young, Faurot, and Gaylord (2009) explored the use of DS among hospital patients, and noted DS usage is common in the United States. Young et al. raised the possibility of DS usage concern among hospital patients, and therefore, determined to assess the degree of patient–physician communication regarding patients' DS usage. The cross-sectional, observational study of 60 hospitalized patients at the University of North Carolina Medical Center revealed although nearly 80% of patients used some form of DS, physicians documented inquiring about patients' usage only 20% of the time.

Twenty-five percent of patients used multivitamins (the DS most used), and 4% of patients used some kind of fish oil. Young et al. (2009) concluded the use of DS in hospitalized patients is common, but patient–physician communication regarding DS usage is limited. Noteworthy observations from this study are the small percentage of physicians who seriously considered DS usage among hospital patients as well as the small percentage of patients who took fish oil (unspecified with respect to the fish oil's DHA and EPA potency).

Underscoring the importance of physician–patient communication, in an interesting Swiss study of 6,133 patients who completed a written survey, researchers Busato and Künzi (2010) determined higher general patient satisfaction, higher expectations of healing, and better physician–patient communication among CAM patients than conventional primary care patients. They concluded better outcomes among

CAM therapy patients. Busato and Künzi asserted effective communication between physician and CAM patients played an important role in patients' expectations of positive outcomes. This research supports the importance of physician–patient communication perhaps relevant to positive long-term outcomes from n-3 dietary supplementation compliance.

Results from another study support how physicians can provide important role models for their patients. Weiner, Swain, Wolf, and Gottlieb (2001) provided an eight-page survey of all 614 internal medicine specialists of the Wisconsin Research Network with an MD or DO degree. The researchers collected survey data from categories of stress associated with medical practice, including self-awareness, sharing of feelings and responsibilities, self-care, developing a personal philosophy, and setting limits. Weiner et al. grouped data into wellness promotion categories, including relationships, religion, self-care, and approaches to life. Regarding relationships, physicians advocated such wellness-promotion practices as being involved in and spending time with family, friends, colleagues, or the community. The religion or spirituality theme included prayer, Bible reading, attending church services, and involvement in church activities.

Self-care activities included reading, good nutrition, avoiding drugs or alcohol, getting treatment for depression, professional counseling, leaving unhealthy relationships, taking vacations, aerobic exercise, hobbies, and meditation. Work activities promoting wellness included medical practice specialty choice, limiting practice size, and deriving meaning from one's vocation. The final wellness category was approaches to life and comprised philosophical outlooks, including positivism, success orientation, maintaining

balance in life, and specific strategies for accomplishing these approaches. Interestingly, according to Weiner et al. (2001), physicians demonstrated increased psychological wellbeing (SPWB) scores when using any of the five wellness-promotion practices when compared with nonusers.

The approach to life practice was associated with statistically significantly higher SPWB scores ($P<0.01$) than the use of any other category of wellness-promotion practice. Weiner et al. (2001) stated the use of wellness-promotion practices by physicians was more consistent with patients' definition of health than with physicians' typical absence-of-disease model. They exhorted physicians to incorporate a broader model of health behavior practices into their own lives to interact more functionally with their patients. Weiner et al. reasoned healthy role models make better healers, because they tend to give advice and interact with patients with more impact and identification.

Also with respect to physician modeling, in a study sponsored by dietary supplement companies, the Council for Responsible Nutrition conducted market research to determine how many physicians took dietary supplements personally and whether or not those physicians recommended the same supplements to their patients (Dickinson et al., 2011). The researchers conducted a survey among 900 physicians and determined 72% of physicians took a multivitamin, but that only 27% took a supplement for heart health including n-3s, vitamins B6, B12, or E. Although one study outcome was 79% of physicians recommended dietary supplements to their patients, Dickinson et al. (2011) did not explain which supplements the 79% recommended, to what kind of patient, or why.

Other studies demonstrated most physicians do not believe they are themselves adequately educated regarding dietary supplements (Adams, Kohlmeier, & Zeisel, 2010; Dickinson et al., 2009) and some may be reticent to recommend dietary supplements to their patients. In this qualitative research study, I gathered information to facilitate understanding why physicians do or do not recommend dietary supplements, what information physicians need, and how physicians make rational decisions to recommend supplements. An educated audience may regard this qualitative study on its own more than a scientific survey because of more value-based, scientific logic (i.e., the medical reasoning or ladders of inference used by medical practitioners). Conclusions from this qualitative study may spawn follow-up, confirmatory quantitative studies.

Factors Affecting Patient Compliance

N-3 marketers should not underestimate the importance of patience compliance as a major physician decision criterion. Patient compliance demographics may also influence n-3 marketers regarding targeted market segments. Olafiranye, Jean-Louis, Zizi, Nunes, and Vincent (2011), affiliated with the State University of New York, Brooklyn Research Foundation on Minority Health, Kingsbrook Jewish Medical Center, and Sophie Davis School of Biomedical Education, concluded a substantive body of evidence suggests patient anxiety independently predicts adverse cardiovascular events. These events include coronary heart disease, stroke, sudden cardiac death, fatal ventricular arrhythmias, and congestive heart failure. Olafiranye et al. cited studies suggesting individuals with anxiety disorders demonstrate unhealthy lifestyles including

unhealthy diets. Individuals with anxiety disorders may be less likely to comply with physician recommendations to change unhealthy diets or take dietary supplements.

Perhaps more troubling, Olafiranye et al. (2011) noted individuals with recent coronary hospital experiences were not inclined to make dietary changes, thereby increasing future cardiac risks. The implication here is physicians' recommendations may not make a difference in health outcomes. N-3 marketers should regard patients in this category as less likely to comply with physician recommendations.

Motivation and understanding also affect patients' engagement in taking responsibility for positive, healthy behaviors. Epstein, Aaron, Baicker, Hacker, and Pauly (2009) discussed the changing landscape of healthcare including the difficulty in understanding the implications of healthcare reform, skyrocketing costs, a physician shortage, patients' habits, engagements, and responsibilities for their own health. Rao et al. (2010) stressed the importance of patients understanding accountability for their own health and underscored the importance of physician-patient communication. Physicians may have work harder to convince unmotivated patients, an important factor for n-3 marketers to consider regarding physician prescribing decisions.

Marketers of n-3s should also consider patient literacy and numeracy as compliance variables possibly affecting physician decisions. Martin et al. (2010) assessed the 10-year risk of coronary heart disease correlated with four literacy skills of 409 subjects. Martin et al. assessed reading, numeracy, oral language, and aural language skills. They found a statistically significant ($p = .001$) inverse relationship between numeracy/aural skills and coronary artery disease among women but not men. However,

study sample bias may have contributed to this gender inequity. Martin et al. noted only 12% of the population has proficient health literacy and rates of cardiovascular death are substantially higher (19.3%) among individuals with inadequate literacy versus individuals with adequate health literacy (7.9%).

Brooks and Pui (2010) suggested numeracy scores were better predictors of patients' abilities to understand health information sometimes vital for life or death decisions. The researchers studied the relationship in numeracy test scores and general mental ability (GMA) test scores because medical practitioners rely upon GMA scores as predictors of patients' understanding of health-related information. Brooks and Pui provided the rational basis and administered the Wonderlic Personnel Test, the Numeracy Scale, the Rational-Experiential Inventory Test, and the Mini-International Personality Item Pool to 200 undergraduates.

Regarding other compliance factors possibly effecting physicians' decisions, Brooks and Pui (2010) found the strongest positive correlations between numeracy and GMA, and between numeracy and rational cognitive style. Numeracy positively correlated with rational decision making, whereas GMA did not. Interestingly, Brooks and Pui reported negative correlations between numeracy and two personality traits: extraversion and neuroticism. They posited introverted, emotionally stable individuals might make better health-related decisions. Brooks and Pui also correlated numeracy and GMA and recommended practitioners consider patients' numeracy scores.

Underscoring the importance of correlating patient conviction to compliance, Nelson, Reyna, Fagerlin, Lipkus, and Peters (2008) presented background evidence low

numeracy inhibits patient decisions regarding preventive medicine choices, reduces medication compliance, impairs risk communication, and affects medical outcomes. Additionally, Nelson et al. reported patients with low numeracy scores are less likely to engage in preventive medicine behaviors and inferior disease management. Finally, they reported low-numerate individuals tend to base medical decisions on short-term benefits and costs rather than long-term outcomes. The implications of this article for marketers of n-3 products are patient consumers with higher literacy scores may be more likely to welcome preventive medicine concepts and comply with preventive regimens. In addition, market segments consisting of patients with higher education levels may be more profitable for n-3 marketers. The implication for physicians' decision criteria is patients with deficient numeracy and literacy skills may require additional effort and monitoring to secure DS regimen compliance.

Patient interest in CAM therapies is another compliance factor. In one study to determine how patient interest in self-care with CAM influenced them to take CAM therapies, researchers Bradley et al. (2011) telephone surveyed 321 patients with Type 2 diabetes. They determined patient interest in trying CAM therapies did not correlate with patient insurance coverage, demographics, clinical status, health history, or self-care behaviors. Bradley et al. also determined patients were more likely to try CAM therapy if they were not satisfied with their current medical treatments for controlling blood sugar.

Additionally, Bradley et al. (2011) determined patients were more likely to try new CAM therapies if they previously used CAM. Bradley et al. determined public interest in CAM therapies has increased in recent years. The implication of the Bradley et

al. study for patient compliance with n-3 dietary supplements is physicians may find more success recommending n-3s to patients positively inclined to CAM therapy or dissatisfied with conventional medicine overall.

In a similar study, Gaul, Schmidt, Czaja, Eismann, and Zierz (2011) explored patient attitudes toward CAM with two questionnaire surveys completed by 432 primary headache patients and 194 low back pain patients in Austria and Germany. Gaul et al. discovered no correlation between patient demographics and CAM use. They determined patients were more likely to use CAM therapies if they had previous CAM experience. Additionally, lack of effectiveness of conventional treatment was another statistically significant CAM use motivation.

Interestingly, Gaul et al. (2011) noted patient concerns about drugs were four times higher among patients inclined toward CAM therapy. In contrast to the Bradley et al. (2011) study where the condition was diabetes with less symptomatic manifestations, the Gaul et al. study consisted of highly symptomatic pain patients. Consistent findings regarding previous CAM use and lack of conventional therapy efficacy drove CAM interest and usage among patients. These factors are important relevant to n-3 treatment compliance.

Another potential factor relates to the study of symptoms. In a Canadian-based study of population patterns in patients who use CAM therapies, researchers Metcalfe, Williams, McChesney, Patten, and Jetté (2010) concluded Canadians appear to use CAM therapies in conjunction with conventional therapies. From a cross-sectional survey completed by 400,055 Canadians, the researchers determined CAM use was higher for

asthma (15.1%) and migraine headaches (19.0%) than diabetes (8.0%). Metcalfe et al. also reported literature review findings of CAM therapy use varying between 6% and 84%. From a literature review, the researchers also reported higher CAM use among individuals with higher income or education levels, women, certain ethnic groups, and those with chronic conditions.

These study results support the hypothesis asymptomatic patients may be less compliant overall, or less compliant with CAM therapies. If generalizable, the relevant decision criterion for physicians relates to compliance. For n-3 marketers, the best candidates for n-3 therapies may be patients with higher income or education levels, women, and those who suffer from chronic, symptomatic cardiac conditions.

Drug and CAM Marketers' Methods to Physicians

To facilitate application and integration of these constructs, provided in this section is an historic and present-day backdrop of marketing methods used by pharmaceutical and CAM marketers. Controversy has surrounded the issue of direct-to-consumer (DTC) drug advertising, especially prescription drugs. Although most n-3 brands are nonprescription, the concerns raised by physicians regarding prescription drug advertising to patients apply to over-the-counter supplements as well.

Historical marketing. In a precedential case of pharmaceutical promotion deception, Landefield and Steinman (2009) discussed misinformation and manipulative practices of Parke-Davis. In 1996, a young, newly employed biologist discovered and reported illegal off-label promotion of Neurontin by Parke-Davis management and sales personnel. Ultimately, the company pleaded guilty and agreed to a $430 million

settlement in 2004 to resolve the criminal charges and civil liabilities. The whistleblowing action highlighted subtle, clandestine approaches to promote off-label use, including dinner programs, continuing medical education courses, consultant arrangements, and personal conversations between sales representatives and physicians. Landefield and Steinman concluded the methods and programs used by Parke-Davis were legal, but noted the prospects for abuse.

To determine DTC benefits and risks, Frosch, Grande, Tarn, and Kravitz (2010) examined proponent and opponent studies from peer-reviewed literature and determined some ads contained accurate and balanced information although some ads were deficient or misleading. Ads frequently did not disclose alternative treatments, risks, or costs, and prompted patients, many with insufficient education or understanding, to request physicians to prescribe an advertised drug. Physicians may not have seen the advertisements for drugs patients requested or were not fully educated regarding new drugs at the time of patients' requests. These situations predispose conflict and Frosch et al. reported results from national surveys where 39% of physicians and 30% of patients regarded DTC as interfering with the physician-patient relationship. Frosch et al. enlightened the potential magnitude of this problem because drug advertisers spent $4.9 billion on DTC in 2007. The authors cited additional survey evidence 89% of physicians claiming DTC increased prescriptions for advertised drugs, some of which are unnecessary.

Frosch et al. (2010) also disputed DTC proponents' claims DTC improves patient adherence (compliance), concluding on balance, overall evidence slightly supported

patient adherence. Perhaps more pertinent, no evidence existed to support DTC results in favorable health outcomes. Considering these factors, Frosch et al. constructed measures to improved outcomes with balanced evidence and regulatory policy. They proposed content guidelines for drug ads including questions regarding candidacy, drug benefits, and drug risks. Frosch et al. provided a detailed questionnaire advertisers should answer with communication understandable by eighth-grade level education listeners.

Nurse practitioners and advanced practice nurses (APNs) can also prescribe and recommend medications and supplements to patients so their opinions regarding DTC pharmaceutical advertising are relevant. In an online survey, 961 Texas APNs responded to two research questions about the impact of DTC prescription drug advertising on patient behavior and quality of care (Mackert, Eastin, & Ball, 2010). Researchers Mackert et al. (2010) reported 49% of APNs believed DTC did not help nor harm the physician–patient relationship. Of the remaining 51%, 31% believed DTC hurt, and 20% believed DTC helped.

Importantly, 69.6% of APNs believed DTCs led patients to request specific drug brands and 57.8% said patients requested switching to the advertised brand. APNs (63.8%) reported DTC drove patient involvement in his or her healthcare, but 57.7% stated the patients demanded inappropriate therapies. APNs (63.5%) acknowledged DTC informed patients to ask intelligent questions but 66.1% of APNs stated DTC caused patient misperceptions and questions (46.2%) about health care advice. Marketers of n-3s may find DTC advertising methods beneficial but should follow the Frosch et al. (2010) guidelines to avoid DTC pitfalls.

Present-day marketing. Approaching DTC prescription pharmaceutical advertising from a constructive educational viewpoint, physician researchers Kaphingst and DeJong (2004) proposed seven recommendations to improve the educational value of DTC advertising. The researchers posed the central question regarding whether average consumers could understand the brief risk messages, often unconsciously diluted by neutral or positive images. Kaphingst and DeJong's recommendations focused upon improving communication and reducing biased, prospectively harmful promotional messages. Specific recommendations included: (a) balance risk and benefit information, (b) use consumer-friendly language, (c) provide additional sources of information, (d) provide text materials geared to the eighth-grade reader, (e) explain more educational information about symptoms and disease, (f) conduct follow-up research to determine consumer ad comprehension, and (g) require prior approval of ads. These points add insight for n-3 marketers.

Using DTC in another channel, marketers of n-3 dietary supplement may employ DTC advertising using the Internet as a promotional strategy. Khosla and Khosla (2011) noted how marketers have replaced traditional forms of drug-product advertising with Internet advertising. They identified OTC medical products as Internet candidates because consumers can purchase these products without a prescription. Khosla and Khosla advocated marketers should employ Internet marketing to educate consumers and advise them when to see their doctors. They noted the importance of balanced, truthful ads informing consumers of potential product risks as well as benefits.

Resulting from a comprehensive review of published and archived literature, physician researchers Greene and Herzberg (2010) evaluated the practices of drug marketers during the 20th century and the effects of these practices upon public health. They reviewed ghostwriting of popular articles, DT drug advertising, public relations events, continuing medical education content, and implicit consumer advertising methods. Greene and Herzberg listed broad social networks used in drug promotion, including artists, journalists, gossip columnists, physicians, filmmakers, medical educators, researchers, science writers, and medical educators.

Greene and Herzberg (2010) explained the difficulty in the century-long consistent flow of complex information to consumers through multiple media and big spending. Although they advocated more regulatory scrutiny, Greene and Herzberg cited the reality of disproportionate drug advertising spending, more than twice the budget of the entire FDA, dwarfing the budget of the FDA office responsible for consumer advertising oversight. Greene et al. advocated ethical transparency among drug marketers and increased regulation of informal and non-advertising forms of drug promotion.

In an article regarding Pfizer's market segmentation methods, Kiron, Shockley, Kruschwitz, Finch, and Haydock (2012) discussed Pfizer's use of analytics and tablet personal computers (PCs) to retrieve field-marketing data daily. A team of 40-50 analysts used this daily information to determine if field representatives were detailing the right physicians, if they were presenting the company's message tailored for the specific physician market segment, and if the presentations resulted in prescriptions. In an interview with a Pfizer executive, Kiron et al. provided an example regarding the

promotional message designed for physicians who treat elderly patients in Florida. Because drug-to-drug interactions are a primary concern among physicians in this market segment, the pharmaceutical representative must deliver the company's promotional message as directed. Immediately after sales calls to physicians, Pfizer representatives must enter conversation details and transmit this information to company analysts the same day. From other data sources (e.g., IMS), Kiron et al. reported analysts can track promotional effectiveness by measuring post-sales-call physician prescribing then using the database information to refine physician customer segments based upon customer preferences and responses to promotional messages.

Relevant to this study, n-3 marketers may use similar practices to Pfizer to define physician customers most favorably inclined to recommend dietary supplements. These physicians may be price conscious, appreciate differentiating efficacy and safety features of cardiovascular preventive health supplements, treat patients with cardiovascular disease, or those physicians who already recommend preventive supplements more frequently than average. N-3 marketers could use databases to develop a holistic marketing approach with historical product-type utilization behavior, reactions to product profile, competitive product use, attitudes toward preventive treatment protocols, and personality traits.

Marketers of n-3s should consider cultural influences when defining customer segments. In an interesting study of cultural influences on a healthy diet, Sun, Horn, and Merritt (2009) analyzed previously surveyed subjects from 25 nations (n = 21,974). The Sun et al. cited evidence of social influencers of dietary behaviors, including family

members, peer groups, health professionals, and mass media; other factors also influenced healthy diet choices, such as living alone, food preference, understanding the diet–health link, high-income residence, and concern for personal appearance. After explicating how elemental personality traits combine with cultural environment to form compound traits (e.g., competitiveness, playfulness, self-reliance, or task orientation), the researchers articulated four emerging cultural dimensions: (a) individualism/collectivism, (b) power distance, (c) masculinity/femininity, and (d) uncertainty avoidance.

Collectivist cultures value group membership. Power-distance cultures advocate social inequality. Cultures favoring masculinity roles include assertiveness, competition, and toughness, whereas femininity roles are oriented toward family, children, tenderness, and home. Uncertainty-avoidance cultures value stability, low stress, and predictability versus change and new experiences.

Sun et al. (2009) determined how public self-consciousness mediated the four cultural dimensions. Public self-consciousness includes physical attributes and concern with impressing others. The researchers determined cultures valuing collectivism (e.g., Japan or Saudi Arabia) are higher in public self-consciousness and concern for goals of group members than cultures who advocate individualism (e.g., Americans). Sun et al. tested the validity of their 4-point Likert scale surveys and determined Cronbach alpha values of 0.81 and 0.76. Their primary conclusion was public self-consciousness positively and statistically significantly correlated with a healthy diet intention ($p = 0.00$). Secondarily, Sun et al. concluded a negative relationship between individualism and public self-consciousness ($p = 0.00$), power distance and public self-consciousness ($p =$

0.00), masculinity and public self-consciousness ($p = 0.00$), and a negative relationship between uncertainty avoidance and public self-consciousness. The researchers noted cultural differences drove 12% of the variance in public self-consciousness and 26% of the variance in a healthy diet intention. Sun et al. also noted power distance was the highest predictor of public self-consciousness. Marketers of n-3s may use these cultural findings to develop market segments.

Weighing cultural influencers against personality trait influencers may facilitate n-3 marketers to define n-3 segments with effective marketing plans. Laura (2011) compared Hofstede's cultural framework to the five-factor model (FFM) to investigate thoughts, feelings, behavior patterns, and preferences among individuals. Hofstede's five cultural differentiating criteria included: (a) uncertainty-avoidance index, (b) individualism index, (c) power-distance index, (d), masculinity index, and (e) long-term orientation index. FFM differentiates among five personality traits: (a) extraversion, (b) agreeableness, (c) conscientiousness, (d) neuroticism, and (e) openness to experience (Laura, 2011). In some circumstances, culture may exert more behavioral influence than personality trait. The relevance of these models here relates to distinct cultural influencers as well as personality tendencies. Marketers should consider cultural and personality trait influencers when defining targeted market segments.

Method and Design

Golafshani (2003) prescribed specific methods for qualitative researchers to establish reliability and validity. Conversely, Holt (1991) rejected the application of objective methods and offered an antithetical, alternative interpretive approach instead of

traditional approaches by others. Golafshani proposed researchers should use methods to substantiate the reliability and validity of qualitative research and researchers should replace traditional reliability and validity vernacular by quality, rigor, credibility, transferability, and trustworthiness. Golafshani acknowledged the researcher should protect the constructivist and naturalistic tenets of qualitative research.

Even so, Golafshani (2003) insisted triangulation and other methods could enhance the rigor of the research without compromising its inherent value. An objectivist approach to qualitative research was possible without altering the reality description expressed by the respondent and interpreted by the researcher. Researchers should employ triangulation for both data collection and analysis and should strive to make their research findings generalizable. A true test of validity is replication by wider groups in similar, if not identical circumstances.

Holt (1991) refuted mainstream qualitative study validity and reliability techniques on the basis such techniques "contradict the nature of the interpretive task, and pose insurmountable problems in application" (p. 59). Holt argued a subject or researcher's individual, contextual interpretation of any event is not verifiable as accurate or truthful. Another individual might relate the same experience differently because of a separate, unique frame of reference and context. Individuals construct whole interpretations from parts, and in addition to contextual interpretation, an individual interpretation of parts emanates from that individual's use of rhetorical words, traditions, political views, and history (i.e., events change as time passes). Holt argued reviewers should employ an interpretive technique and judge interpretations by the insight provided

and the power to convince (Thompson's gestalt experience, as cited in Holt, 1991). Holt posited if enough peer experts agreed, the consensus would define the predominant interpretation.

Holt (1991) and Golafshani (2003) both emphasized the importance of preserving the naturalistic benefits of qualitative research. Both drove convincing arguments the reliability and validity criteria used for quantitative research are not applicable for qualitative research, although Golafshani embraced the concepts, but used different labels. Both authors cited other reputable sources who advocated reliability and validity testing for qualitative research.

For example, Holt (1991) discussed traditional methods of testing naturalistic inquiry including credibility, transferability, dependability of measure, and conformability. Holt added a fifth criterion, integrity, citing Belk, Sherry, and Wallendorf (1988). Holt explicated the 10 recommended techniques of Belk et al.: (a) prolonged engagement and persistent observations, (b) use of triangulation with different researchers for data collection and interpretation, (c) frequent on-site team interaction, (d) negative case analysis, (e) peer debriefing, (f) member checking, (g) limiting exceptions, (h) purposeful sampling, (i) reflexive journals, and (j) independent audits. Golafshani (2003) cited additional authors who advocated validity techniques by different names that enveloped reliability at the same time. Neuman (2011) advocated applying similar criteria to those recommended by Belk et al.

Other authors advocated similar methods to add validity to naturalistic and qualitative research, some with more detail. Bernard and Ryan (2003) outlined eight

observational techniques and four manipulative techniques for unbiased theme development. Shepherd and Rentz (1990) provided steps "to minimize the subjectivity of coders" (p. 62). Scott-Jackson, Druck, Mortimer, and Viney (2011) discussed interviewing techniques to guard against bias and reactivity, threats to validity. Brent and Slusarz (2003) recommended computer assistance "to assess and improve the reliability of coding by the researcher" (p. 299). Last, Zelik, Patterson, and Woods (2010) proposed a model with eight specific components to establish rigor and prevent shallow analysis in qualitative research. Zelik et al. observed just because researchers employ the word *rigor* as a justificatory warrant for their studies, does not necessarily provide assurance.

The preponderance of evidence and opinions of experts drive the need for doctoral students to employ robust methods in qualitative research to establish and maintain research project validity. At the same time, researchers should appreciate and maintain the naturalistic benefits intended by qualitative methodology. The five criteria, 10 methods, and the rigor scale are useful elements to ensure trustworthiness and credibility in qualitative research studies.

Shepherd and Rentz (1990) presented the critical incident technique. With respect to content analysis, they presented specific techniques regarding coding schemes and code processing. Shepherd and Rentz emphasized the coding scheme should reflect the purpose of the research and the scheme should emerge gradually as the researcher becomes familiar with all the accumulated data. They also discussed minimized coder subjectivity by using a small unit of analysis (e.g., simple word or smallest phrase),

employing mutually exclusive response categories (e.g., black or white, not both) and maintaining the independence of the codes so the codes are not linked.

Shepherd and Rentz (1990) presented a compelling argument the word *rigor* is often platitudinous rhetoric as applied to qualitative data. They provided eight examples of shallow analysis and presented an alternative chart with eight attributes as criteria to determine low, moderate, and high rigor. The eight attributes included hypothesis exploration, information search, information validation, stance analysis, sensitivity analysis, information synthesis, specialist collaboration, and explanation critique. Shepherd and Rentz indicated researchers can use the eight attributes as measures to prevent shallow analysis but 10 or more contextual factors influence the judging of rigor sufficiency.

Bernard and Ryan (2003) asserted theme development is a mysterious process and researchers typically lack instruction and skills for discovery and consistency. They identified four important tasks in theme development: (a) discovering the themes and the subthemes, (b) limiting themes for practicality, (c) building theme hierarchies, and (d) linking themes to theories or models. Bernard and Ryan noted themes must be visible in data, may be symbolic, culturally dependent (contextual), and derived from codes. They outlined 12 techniques, eight observational and four manipulative, to facilitate competent theme processing.

Themes emerge from coding. Brent and Slusarz (2003) advocated the use of qualitative analysis programs to facilitate coding of typically voluminous transcribed data. Researchers benefit from coding software applications because the software can

enhance reliability, limit missed codes, and reduce researcher time and workload. Brent and Slusarz analyzed the coding process and disclosed computational strategies as case-based reasoning, natural-language generation, semantic networks, and production rules. Brent and Slusarz stated programs learn and become more valuable to the researcher as the program amasses transcribed information garnered from observations or interviews.

Qu and Dumay (2011) differentiated interviewing perspectives, and therefore, data interpretation and thematic development, based upon the interviewer's worldview. They defined the neo-positivist, romanticist, and localist perspectives. With some overlap among categories, Qu and Dumay argued neo-positivists use structured interview technique and study facts, romanticists use unstructured interviews and focus upon meaning, and localists use semistructured interviews to focus upon context and the interviewee's account of events. Interviewer worldview and technique therefore influences data interpretation and thematic development.

Considering different worldviews and interview approaches used by qualitative researchers, Qu and Dumay (2011) reported how quantitative researchers regard qualitative interviews as unreliable and subject to bias. Qu and Dumay emphasized how careful interview preparation, use of competent interviewing skills (e.g., questioning, listening, dyadic conversational skills, etc.), and protecting against asymmetrical control can produce a rich data set. Qu and Dumay stated no one interview approach is right, no single format is appropriate for each interview, and the same questions will not always work. The unique compositional experience of each interview can affect data collection: the personality of the interviewer, the perspective of the interviewee, and the interview

setting (Qu & Dumay, 2011). The collection of data, its coding, thematic development, analysis, and interpretation, together present a complex task to optimize desired meaningful study outcomes. Those desired outcomes include a clear understanding from study subjects to formulate effective communication for educating physicians and influencing n-3 prescribing behavior.

Regarding educating physicians, Legare et al. (2011) noted the role of continuing professional development (CPD) as a primary process physician generalists and specialist use to stay current and improve knowledge and skills requisite for patient care optimization. Legare et al. developed a global instrument to assess the value of CPD activities on clinical practice. Legare et al. verified the acceptability and value of CPD instruments, what features needed revision, and what CPD instrument content needed deletion or addition. Both immediately following completion of CPD and two weeks later, session participants completed the assessment tool to rate aspects of the CPD program. Two overriding principles promulgated by promoters of the KTA process for healthcare professionals guided program success determination: the knowledge creation cycle and the action cycle.

Adding credibility to the action cycle concept in KTA, Rodriguez, Marquett, Hinton, McBride, and Gallagher-Thompson (2010) studied action plans as a follow-up tool to assess changes in clinical practices after training. One study objective included the assessment to change barriers. Three months after clinical training, 73% of respondents acknowledged action plans stimulated specific behavioral changes in clinical practice. These results highlighted the importance for including action plans in the methods and

design of the present doctoral study. In the present study, therefore, I included a specific follow-up question to determine if respondents increased their recommending of n-3s as a study outcome to drive real, effective, behavioral, and clinical practice change.

Psychological cognition mechanisms precede behavioral change and Cova, Dupoux, and Jacob (2010) explained pure scientific models consisting of desire and intentions as psychological states cannot explain human behaviors. Cova et al. (2010) reasoned behavioral models are also deficient because these models do not include a moral causal variable and therefore cannot correctly predict human intuitions or actions. Depending upon context, cognition, and the decision-maker's moral compass, an individual may decide consciously to take action (or refrain from taking an action), which baffles the logic of observers. This explains how individuals can initiate behaviors others regard as illogical, but to the individual, the behavior is irrefutably and morally right. Important for n-3 marketers, supported by data collected from interviews in this study, physicians consider moral rightness when making decisions.

Transition and Summary

Section 1 was an introduction to possible n-3 health benefits, the business problem of marketing n-3s, the research questions, and qualitative study design and methods I used to drive study outcomes and answers to research questions. The outcomes of this study may fill gaps in understanding physician prescribing decision processes. If 120,000 Americans die each year prematurely from cardiovascular disease (CDC, 2011) and if the daily ingestion of the proper ratios of n-3 can reduce cardiovascular disease by 19% to 45%, the prospective societal benefits of this doctoral study are substantial.

Study outcomes may facilitate n-3 marketers' sustainability and profitability because an improved understanding of physician prescribing decisions may improve effective communication with physicians resulting in physician prescribing behavior change. Increasing preventative medicine behavior among physicians in this capacity will enhance public awareness and society's cardiovascular health. These study outcomes are consistent with the Walden University DBA Doctoral Study rubric. Section 2 includes more study method detail regarding the role of the researcher, data collection, and data analysis.

Section 2: The Project

Purpose Statement

In this qualitative, phenomenological research study, the purpose was to improve n-3 marketers' understanding of how physicians reach decisions to prescribe or recommend products, including omega-3 (n-3) dietary supplements and which product characteristics may be the most important to physicians. I explored physicians'n-3 dietary supplement knowledge and decision criteria (ladder of inference; Argyris, 1976) and found physicians' inference ladders for prescription drugs are similar to physicians' inference ladders for n-3s. The education of physicians and the ladders of inference physicians cognitively ascend determined their n-3 prescribing/recommending choices. By understanding these complexities, n-3 marketers will be able to develop effective learning instruments and promotional tools (predictors) to influence physicians to recommend patients comply with a daily dosage regimen of quality n-3s containing adequate DHA and EPA concentrations (criteria).

In Kentucky, Indiana, and Tennessee, I interviewed 20 primary care physicians. According to Ashar and Rowland-Seymour (2008) physicians are opinion leaders because of their primary influences over patient health thereby justifying the selection of physicians as participants in this study. The study objective was to answer the primary research question regarding what ladder of inference physicians use to recommend dietary supplements, especially n-3s. Another study purpose was to gather useful physician marketing strategy information regarding n-3s and cardiovascular disease reduction. The business implication was to facilitate n-3 marketers' understanding of

physician customer thinking and needs. An increase in physician education may culminate in more preventive medicine behaviors by physicians, augmented marketing effectiveness of n-3s, increased n-3 use among the general population resulting in improved health, reduced cardiac disease, and reduced U.S. healthcare spending.

Role of the Researcher

The role of the researcher, in this data collection process, was to interview the study participants. Using a digital recorder, I recorded the interviews and a qualified assistant transcribed the interviews verbatim. I enlisted coding services from a second coder to code the transcripts and develop themes to increase internal validity (Bertolotti & Tagliaventi, 2007). Transcriber and coder assistants signed *Confidentiality Agreements* and an IRB approved their participation.

Chenail (2011) emphasized the important central role of the researcher who serves as the research instrument, primary collector of data, driver of investigator-subject contextual interactions, facilitator of communication flow, and conveyor of interview atmosphere and communication ease. In this role, if a study subject is reticent to talk openly, the researcher should ask open-ended questions and prevent open-ended questions from turning into closed-ended questions. As the primary data collection instrument, the researcher is also the primary threat to study trustworthiness and source of bias. Interviewer/researcher bias may occur with the researcher's abnormal psychological state or discomfort with the study subject, lack of preparation, or inappropriateness of interviews.

The process of qualitative research requires a fully immersed investigator. Sergi and Hallin (2011) noted the application of ontology to qualitative approaches, where the researcher's experience is deeply emotional and personal, necessary to reveal the richness of the situation. Sergi and Hallin posited although some may describe qualitative research as a linear, step-by-step procedure, the qualitative approach is inherently a lived researcher's whole-self experience whereby the researcher feels the emotions and perspectives of the study subjects. Through this lived experience including its affective facets, the researcher gains a richer image of the subject matter and goes closer to the real-life experience.

Sergi and Hallin (2011) emphasized that the researcher's experience is an inevitable part of the research study and is therefore a thick performance. This framing is fundamental to understand and address bias. This understanding also accentuates change and practice as fluid elements in qualitative research: change because study subjects continually evolve and practice because, by definition, practice involves the researcher's thinking, skills, and rationality, but also the researcher's emotion, body, power, intuition, and a contextual interpretation. Sergi and Hallin differentiated their emphasis of the researcher's performance from autoethnography. Autoethnography assumes the researcher's experience automatically derives from a cultural connection with the subject. Rather, acknowledging the importance of the researcher's role with personal emotions expands transparency and understanding of reflexivity, imagination, and ethics.

Participants

I obtained access to research participants through published physician list records. The purposeful sample consisted of physician subjects interested in the study subject, acknowledged an open perspective regarding diverse opinions specified in the signed *Informed Consent* document, and who were accessible. I selected participants in three targeted states with whom I did not develop personal relationships previously.

I protected participants through informed consent (see Appendix C) and protocol implementation approved by an institutional review board (IRB). Before commencing any data collection, subjects understood, signed, and returned *Informed Consent* documents to the interviewer. This group of medical professionals understood principles of ethical research.

Research Method and Design

In the sections below, I describe the research method and design as follows: (a) description of research method and design, (b) justification of method and design, and (c) relevancy to the business problem statement. The method and design were appropriate with respect to the problem statement. This subsection is an expansion of Nature of the Study in Section 1.

Method

This qualitative method was appropriate for this marketing topic. Smith, Bekkar, and Cheater (2011) discussed the difficulties of choosing qualitative research methods in topics involving health care because most researchers use quantitative methodology. Smith et al. advocated researchers should employ qualitative methods to explore

complexities affecting health, including economic, social, environmental, and political factors. Bekkar et al. also advocated qualitative methods as adjunctive to quantitative methods. They reasoned qualitative methods can expand the investigator understanding.

After discussing the problems of fit with ethnographic, phenomenological, and grounded theory designs, Smith et al. (2011) recommended a generic approach to researcher using qualitative methods in health care. Smith et al. reasoned investigators who maintained an open, holistic perspective rather than pursue evidence to support a predetermined theory would enhance credibility among readers in the medical community. Although I intended n-3 marketers as the primary audience of this marketing study, some in the medical community may find the outcomes of this study relevant and useful (e.g., physician impressions of their own knowledge of dietary supplements).

Research Design and Method Justification

In this study, I followed important guidelines that were recommended by Malterud (2001), who observed some members in the health care community are skeptical regarding qualitative research, citing the perceptions of subjectivity and absence of facts with qualitative research methods. Malterud posited qualitative research findings could be important in health care and outlined important processes for qualitative researchers to enhance acceptance by members of the health care community. Malterud noted the difference in procedure for data interpretation but underscored similar research principles, including relevance, validity, and reflexivity as overall standards for qualitative inquiry. Malterud also warned of the challenges presented with reflexivity, transferability, and interpretation assumptions, criteria emphasized by members of the

health care community. Malterud that noted researchers must be prepared to answer questions regarding their findings and interpretations, internal and external validity, context and bias (explaining the value of contextual interpretation), and data analysis processes.

Regarding interpretation and analysis, Malterud (2001) advocated a thorough analysis, including a discussion of valid, alternative interpretations. Proper data analysis includes decontextualization and recontextualization. Decontextualization extracts portions of data for scrutiny and compares these units within the holistic context of the rest of the data. Recontextualization confirms the consistency of patterns within the study context (Malterud, 2001).

The researcher-emphasized knowledge does not emerge from data only, and researchers must include empirical substance and theoretical bases to form valid conclusions. Malterud (2001) emphasized researchers who fail to acknowledge theory and claim an inductive approach reduce credibility because theory influences all researchers. Last, to enhance qualitative study trustworthiness, Malterud advocated a transparent path description from data collection to findings in the research report to facilitate readers' understanding of research procedures.

Accentuating the lower opinion of some health care community members regarding qualitative research, researcher Beck (2009) emphasized evidence-based practice, including critical appraisal of evidence. Beck ranked highest the quantitative systematic reviews of RCTs. Beck posited critics rate qualitative studies lower than quantitative studies because researchers do not base evidence upon statistics. Researchers

who employ quantitative methods use data collection instruments validated to strict standards whereas qualitative method researchers use perceived subjective instruments. Beck advocated qualitative studies as useful to enhance understanding of patients' lived experiences and described five trustworthiness criteria to use when evaluating qualitative studies. Consistent with Beck's thinking, the outcomes from this phenomenological research study can enhance n-3 marketers' understanding of physician prescribing and recommending decisions.

Al-Hamdan and Anthony (2010) provided a useful contrast between positivism and post-positivism research approaches. Positivism is the foundation for quantitative methods, whereas post-positivism is the foundation for qualitative methods. Al-Hamdan and Anthony described positivists as committed to transferring the precepts of naturalism and natural sciences to the social study objectives as a conceptual unification of methods. Positivists approach social science data as undeniable facts and attempt to apply scientific laws to establish truth. Al-Hamdan and Anthony positioned positivists as those who study the social world with a hypothetic-deductive method to find objective data through natural-world observations. Critics of the positivist approach state the approach does not allow the researcher to examine human behavior in depth.

Conversely, Al-Hamdan, and Anthony (2010) described postpositivist researchers as interpretive sociologists focused upon studying the individual who are active and mindful of contextual surroundings, able to make independent choices. Although postpositivists consider observed and real lived experiences of subjects, they do acknowledge the existence of the metaphysical as beyond individuals' physical senses.

Postpositivists engage in rich, holistic analysis not in positivist research approaches. Al-Hamdan and Anthony identified reality influencers such as culture, gender, and beliefs.

Al-Hamdan and Anthony (2010) cited postpositivist research critics who described qualitative researchers as those who present interesting stories with isolated, potentially biased findings not advancing the discipline, because they do not spur further reproductive research to establish external validity. In this study, the qualitative design and interview methodology were relevant to finding important information to solve the stated business problem. Learning how physicians make prescribing decisions constituted more than presenting interesting stories. Employing the methodological techniques described above facilitated the objectivity and unbiased findings of the study. Open-ended exploratory interview questions with follow-up clarifying questions yielded information specific enough and relevant enough to enable significant meaning to study outcomes regarding the articulated business problem.

Population and Sampling

The study population included physicians who practice primary care and cardiovascular medicine worldwide. The purposeful sample in this study included primary care physicians in a limited geography (Kentucky, Indiana, Tennessee). The sample size was sufficient ($n = 20$) because I did not gather significant new information after the 15th interview, evidential I reached saturation in less than 20 interviews. Saturation is a guiding principle of sample size determination in qualitative studies (Carlsen & Glenton, 2011). Mason (2010) argued saturation is elastic and true saturation is contingent upon a number of variables including the aims of the study, homogeneity of

participants, and skill of the interviewer. Consistent with Mason's factors affecting saturation, the focused aims of this study, similar specialties among physician subjects in a limited geography, and richness of data gathered during interviews support the possibility of achieved sample saturation for this defined population.

Kerr (2010) stated investigators cannot predict saturation but for practical purposes, investigators need to plan number of subjects. From past studies, Kerr determined investigators who sought to establish sample size guidelines for qualitative methods of inquiry advocated samples sizes of six to 20 subjects. Similar to Mason (2010), Kerr stated saturation depended upon heterogeneity of subjects and study objectives. These guidelines supported the purposeful sample size for this focused physician decision-criteria marketing study. Further justifying the sample size and intent of this study, Bloomberg and Volpe (2012) advocated studying a small number of subjects for phenomenological study investigators to conduct deep inquiry and collect thick, rich data thus reducing the need for a larger sample.

Data Collection

Instruments

With respect to data collection, I followed the advice of scholarly investigators. Rubin and Rubin (2012) advocated *responsive interviewing* to uncover and examine complex, hidden phenomena. Responsive interviewing emphasizes the mutual involvement of both the interviewee and the interviewer essential to derive meaning. To derive reliable and valid meaning, the interviewer must build a reciprocal relationship with the interviewee and demonstrate respect to create a conversational partnership.

Similarly, Denzin and Lincoln (2008) underscored the importance of an intimate relationship and resultant participatory engagement between the interviewer and interviewee.

The interviewer must remain cognizant of emotional effects of the interview on both parties and prevent biases by acknowledging potential areas of vulnerability and data contamination. By using main questions, probes, and follow-up questions, the interviewer can drive in-depth interviews to facilitate understanding of the obvious and unobvious aspects of complex human behavior and collect rich, thick, data. The interviewer should employ main questions to structure the interview, probes to elicit more specifics and maintain conversation flow, and follow-up questions to explore comments and ideas emerging during partnership conversations (Denzin & Lincoln, 2008).

In a relevant study in which investigators used subjects' words to develop themes related to CAM therapies, Ritenbaugh et al. (2011) developed outcome instruments derived from patients' words instead of preexisting theory. The researchers produced a final questionnaire consisting of 18 items. These items included assessments of positive and negative self-perceptions in the following outcome domains associated with CAM therapy compliance: physical, social, psychological-cognitive, psychological-affective, spiritual, and whole person. In this study of physician decision criteria, physicians used words indicative of similar domains. Therefore, the Ritenbaugh et al. study outcomes provided a useful framework for understanding physician subject responses.

To test the quality of the interview protocol and as a safeguard against researcher bias, Chenail (2011) proposed a pilot study to test planned interview questions and procedures as well as interviewing-the-investigator technique. I used both tests in before conducting this study. Chenail specified the qualifying criteria for interviewing the investigator as the investigator must be part of the study subject population or have a strong understanding of the study subjects. A pilot study requires IRB approval with human subjects, achieved in this study. Interviewing-the-investigator method does not require IRB approval.

The benefits of pilot studies include finding weaknesses or possible failures and determining if the interview questions are vague, irrelevant, unproductive, or too complicated. Pilot studies also provide the interviewer an opportunity for practice, obtain feedback from subjects regarding the questions, determine interview duration, and revise or edit questions. Chenail (2011) noted data collected during the pilot study is typically not included in the main research study. The pilot study included an in-depth interview using planned study interview questions (see questions listed below in Data Collection Technique section). The pilot study subject answered questions regarding the effectiveness of planned interview questions.

Subject answers to interview questions and interview procedure informed planned field research (Chenail, 2011). During the pilot study, I practiced interview and follow-up question administration, test audio recording procedures and function, and received feedback from the pilot study subject (Neuman, 2011). I also explained study

background, consent form including risks, benefits, and privacy, study methods, and study procedures to the participant.

To test the instrument in this doctoral study, I also used interviewing-the-investigator technique and tape-recorded the process. Regarding practical steps for interviewing the investigator technique, Chenail (2011) explained the investigator can play the role of the interviewed subject only, or play both roles (interviewer and interviewee). Chenail advised the investigator may enlist the help of a colleague or faculty chair to accomplish this process. Chenail recommended a cyclical process to incorporate ideas emerging during the trial interviews until no further changes evolve during the process.

A unique benefit of interviewing-the-investigator technique is the investigator experiences the thoughts and feelings of the interviewee (study subject). The investigator should document any feelings or discoveries of potential biases with corrective actions because the IRB will analyze the investigator's pre-study steps to determine instrument rigor. Finally, the interviewer should identify and document pretextual, subtextual, and contextual factors to control response divergence (Csordas et al., 2010). These two instrument tests increased my awareness of voice intonation, placement of audio recording device, revised question sequence, and improved my skill in using impromptu exploratory and clarifying follow-up questions.

Data Collection Technique

Study subjects heard interview questions for the first time during live interviews. I audio recorded each interview. In addition to audio recordings, I made written notes to document subjects' main responses to questions.

To determine interview format for this study, I considered Turner's (2010) interview design descriptions: (a) informal conversational interview, (b) general interview guide, and (c) standardized, open-ended interview design. According to Turner, most critics regard the informal conversational interview as unstable and unreliable. The general interview guide approach allows an interviewer freedom to ask questions using personal style or paraphrase. To minimize inconsistent responses from study subjects, I did not use the general interview guide approach. According to Turner, the best format is the standardized open-ended interview, because the interviewer asks participants identical questions with additional probing questions for clarification. This procedure reduces researcher bias and is the interview protocol I used for this study.

Turner (2010) provided suggestions for conducting qualitative interviews, including preparation, participant selection, pilot testing, effective research construction, follow-up questions, and interview implementation. Turner's other ideas include selecting participants who will be willing to share their story honestly, avoiding evocative or judgmental wording in open-ended questions and not asking *why* questions or asking them with care. Turner advised flexibility by the researcher if a subject does not answer a question (i.e., come back to the question later in the interview) or if the subject answers a question before the interviewer asked the question. The interviewer should also be

prepared and ready to ask immediately follow-up questions, consistent with the interview protocol planned for this study.

Demonstrating a model for interviewing physicians and other clinical staff, Curran et al. (2012) conducted qualitative research using interview data collection methods to test the effectiveness of an intervention for anxiety: Coordinated anxiety learning and management (CALM) in 17 U.S. primary care clinics (n = 47). The investigators trained the interviewers prior to study inception. The interviewers employed a core group of nine questions included in the interview guides. Prior to the study, a group of investigators decided upon the questions after revising the questions several times, including question revision after interviews had begun. The interviewers asked open-ended core questions to determine facilitators and barriers to implementing CALM.

The interviewers also used open-ended questions to find the facilitators/barriers to sustaining CALM after study completion. Interviewers recorded the conversations, subsequently transcribed verbatim. Curran et al. (2012) reported in two instances, the transcriber used the interviewer's notes because the audio tape-recorder malfunctioned, which highlights the importance of interview note taking I used in this study.

Curran et al. (2012) designed the interview protocol to support conventional (inductive) and directed (a priori) content analyses. In this respect, the protocol included a mixture of overview questions (e.g., "Tell me about your role and involvement in the CALM project") and specific follow-up probes designed to facilitate contextual understanding, procedures, peer influences, and attitudes. Curran et al. (2012) explained they designed interview questions to encourage subjects' open expressions. This

approach subsequently enables data analysts to focus upon describing phenomena freely without constriction to a specific theory or behavioral model. Interview questions also elicited data later subjected to directed content analysis whereby investigators explored predetermined themes and concepts leading to predetermined codes. Curran et al. noted their emphasis on inductive data collection, applicable and used in this study.

I followed the suggestions of Skirbekk and Nortvedt (2011), who demonstrated relevant qualitative study interviewing methodology in a medical setting. The purpose of their study was to understand medical professionals' conflict between care and concern for particular patients versus impartial considerations of justice, which become central to moral deliberations. From interview results conducted with physician and nurses in Norwegian hospitals (n = 21), Shirbekk and Nortvedt discovered the dominant value norm: making differences for patients. Nurses, more than physicians, based their care decisions upon patients' subjective needs.

In vacant hospital offices assisted by audio recording technology and a notebook, Shirbekk and Nortvedt (2011) conducted interviews. Subsequently, transcribers converted taped interview content verbatim. In this study, too, interviewers followed a specific interview guide. In a consistent theme, they designed the interview questions to facilitate open discussion and reflection upon phenomena of common interest.

Shirbekk and Nortvedt (2011) described their technique as active interviewing, with both the interviewers and interviewees epistemologically active, participating in the process of making meanings. The trained interviewers encouraged nurses and physicians to reflect upon their own experiences, tell their own stories, and assert their own opinions

regarding the subject phenomena. Shirbekk and Nortvedt explained the roles of the interviewers as more than reporting subjects' responses. They emphasized the interviewers' active interview participation.

To document the process of active interviewing, Shirbekk and Nortved listed specific questions asked during the interview process. Most questions were open-ended. For example, interviewers asked subjects what they considered just treatment, what were just priorities, how they set priorities, and how they dealt with patient priority conflicts. Additionally, the researchers developed interview questions to explore how often they discussed such priorities with colleagues, expectations from colleagues and hospital executives, and their sense of responsibility for their patients. These questions and interview methodology are relevant models for the present n-3 study.

Scheermesser, Bachmann, Schämann, Oesch, and Kool (2012) provided a valuable schematic to depict the circular process and long-time requirements for competent data collection and analysis. Scheermesser et al. described the process to encompass six quality criteria of qualitative research. These criteria included: a) documentation of the data collection procedure, b) validating interpretation by argumentation, c) systematic, dyadic procedure, d) closeness to research object, e) validation by coder and author communication, and f) triangulation of methods. Interestingly, Scheermesser et al. portrayed a circular, dynamic process to accomplish triangulation after collecting data from a purposive sample through interviews, in-depth interviews, and focus groups. The authors reviewed collected data repeatedly to define codes reliably, identify themes, and argued to increase the robustness of their discoveries.

The Scheermesset et al. (2012) study example demonstrates how qualitative research methodology is inductive rather than deductive because the nature of the research seeks descriptions of people and their particular situations, meanings, and experiences. The qualitative research process is antithetical to quantitative research in the respects qualitative research is nonlinear and nonsequential. The findings of the aforementioned investigators influenced my selection of the qualitative method and guided interview-question design in this study.

The specific interview questions were:

1. Considering the previously explained ladder of inference and reflexive loop (Ayers, 2002), what processes do you go through to determine what products you will prescribe or what dietary supplements you will recommend?
2. What credible clinical evidence have you seen regarding fish oil dietary supplements?
3. What made the evidence credible or incredulous?
4. What are the risks of taking fish oil dietary supplements?
5. What are the risks regarding specific patient groups or disease states?
6. What are the important differences between quality fish oil dietary supplements and low quality fish oil dietary supplements?
7. What are right daily amounts of DHA and EPA?
8. If clinical evidence is credible and convincing regarding fish oil efficacy for health prevention for disease amelioration, what education and communication methods to physicians are best?

9. Similarly, what education and communication methods to patients are best?

10. Within the context of the ladder, please explain your present professional opinion regarding the health value of fish oil dietary supplements, specifically fish oil containing n-3s, for patients with no contraindications.

11. What are your prescribing or recommending practices regarding n-3 fatty acid dietary supplements and the priority of n-3 dietary supplements as compared with other dietary supplements (e.g., multivitamins, chondroitin, niacin)?

12. How influential are your peers' prescribing practices to your decisions?

13. When you speak with your peers, what percentage of them would you say are committed to frequently recommending omega-3s?

14. If all your patients took a high quality omega-3 every day, what would be the impact on your whole practice?

15. If all your patients took a high quality omega-3 every day, what would be the positive impact on U.S. healthcare costs?

Data Organization Techniques

After data collection, I organized subject responses and audio recordings by individual study subject files. I stored the raw and transcribed data in a locked office with limited access controlled only by me. I plan to dispose of subject data using a shredder after 5 years. Both during and after the study, I preserved physician subject confidentiality.

Data Analysis Technique

Data analysis links to the conceptual framework of the study. I analyzed data in the context of ladder of inference theory. Data analysis facilitated physician self-understanding and helped identify physician and patient needs for education and marketing purposes. I identified themes from recurring subject statements coded and checked by another coder. Data complexity and diversity did not warrant hyperRESEARCH software to facilitate code development.

Relevant to coding, thematic development, and data analysis, unconscious mental processing of data—reflective processing—was a vital, necessary part of this qualitative research because of the discovery of important but unobvious underlying psychological constructs (Meek, 2003). I experienced this phenomenon often overlooked by other researchers, according to Meek. The reflective process includes both intellectual and emotional components, where often the gut feeling and intuition catalyze the researcher's conclusions or decision to proceed to the next step (e.g., not adding more codes but proceeding to thematic development and analysis). Reflective process has its roots in psychoanalysis, wherein Freud differentiated among the conscious, preconscious, and unconscious minds (Modell, 2011).

According to the psychotherapist Meek (2003), understanding the workings of the unconscious mind of subjects provides opportunities to deepen understanding and discover unobvious mechanisms of motivation and reasoning. The psychotherapist describes the workings of the unconscious mind as highly complex, forming associations of disconnected concepts not necessarily in chronological order, and disassembling and

assembling ideas not logically related. Meek provided instances of the unconscious mind at work: Working on an unrelated jigsaw puzzle sometimes triggers a solution or an idea relevant to a different dilemma or how awaking from a night's sleep provides new insights and revelations.

Meek (2003) outlined pragmatic steps for reflective processing for researchers to follow. Researchers should break complex material into stages, make repeated passes at the data to find new revelations, and translate material using own words to articulate new ideas. When the researcher is stuck, one should understand any relationship between personal conflict and the research topic and identify those links to facilitate understanding. Second, Meek advised researchers to take breaks. Because the unconscious mind requires time to finish combinatory play, the researcher should not always regard a time of perceived unproductivity as wasted time. Meek exemplified how fallow fields regenerate during the time microorganisms regenerate themselves, which prepares them for the new season.

Third, Meek (2003) advised the researcher should gain differing perspectives about the data by looking at data from a distance. Sometimes researchers become too engrossed in data detail. Fourth, the decision to integrate versus deconstruct data is an intuitive one. Meek posited researchers realize this point when their curiosity is satisfied. Discoveries of the unconscious mind can be valuable, but reflective processing requires a conscious stepped approach, and the steps are not necessarily sequential. This advice served me well because during quiet and reflective times I sometimes found frustrating, I

could organize subject responses cognitively into themes and developed a hierarchical order of presentation (consistent with ladder of inference theory) for the study report.

Regarding specific coding methods, Li and Yeo (2011) provided specific coding steps as a useful model. They initially established categorical cues grouping research questions as broad categories and the follow-up probes as root categories. Li and Yeo employed key word searches (e.g., quality, commitment, team, reward, etc.) to garner an overall view of the data. Their next step was to identify clusters of information relevant to the study purpose of inquiry.

Following the formation of information clusters, Li and Yeo (2011) engaged in a rigorous and systematic patterning process until they observed recurring themes. They also grouped examples provided by subjects with the recurring themes. By using categorical cues and classification tables, Li and Yeo developed units of analysis and thematic patterns. Evolving to analysis, they adopted an integrative purpose to reduce responses to clear collective sets. Li and Yeo matched the collective theme sets to their research questions and themes identified in literature. They emphasized three comparative analysis steps to enhance the trustworthiness of the data: (a) derivation of research questions and issues from related literature, (b) rigorous coding adherence to established coding system, and (c) inter-coder involvement and verification to ensure reliability. I used all three steps in my analysis.

Reliability and Validity

Reliability

Beck (2009) proposed five trustworthiness criteria appropriate for qualitative studies including credibility, dependability, conformability, transferability, and authenticity. I described all these criteria in previous document sections, except authenticity. According to Beck, authenticity is the degree the researchers fairly and truthfully described study subjects' experiences. I increased authenticity and credibility by validating transcribed data with participants through e-mail follow-up as a method of member checking.

Beck (2009) also provided a list of 57 valuable questions a medical professional should employ to assess study trustworthiness. The questions pertain to study-report sections, including the title, abstract, introduction, methods (sample and setting, data collection, procedures, enhancement of rigor, etc.), results (data analysis and findings), discussion, and global issues (presentation, researcher credibility, and summary assessment). These questions guided my development of this doctoral research study. Parenthetically, to enhance understanding of the medical professional's foundational ideology for evidence-based practice, Beck advocated (a) asking the burning question, (b) collecting the most relevant evidence, (c) critical appraising clinical evidence, (d) integrating evidence with personal experience, expertise, and patient preferences and values, and (e) continuing evaluation of the medical decision and change in health status. I followed Beck's recommendations in this study and determined two compelling

questions relating to the cost of drug or dietary supplement therapies and the personal experiences of physicians.

Validity

Regarding qualitative research, Golafshani (2003) proposed researchers should replace traditional validity vernacular by quality, rigor, credibility, transferability, and trustworthiness. Golafshani insisted triangulation for both data collection and analysis could enhance the rigor of the research without compromising its inherent, naturalistic value. Golafshani also advocated qualitative researchers to make their research findings generalizable, and a true test of validity is the reproducibility of study findings in wider groups and similar, if not identical, circumstances.

Holt (1991) essentially refuted mainstream qualitative study validity and reliability techniques on the basis that such techniques "contradict the nature of the interpretive task, and pose insurmountable problems in application" (p. 59). Holt argued a subject or researcher's individual, contextual interpretation of any event is not verifiable as accurate or truthful because another individual would relate the same experience differently because of a separate, unique frame of reference and context (e.g., the Roshomon parable). Holt argued reviewers should employ an interpretive technique and judge interpretations by the insight provided and the power to convince (Thompson's gestalt experience, as cited in Holt, 1991). Holt posited if enough peer experts agreed, the consensus would define the predominant interpretation.

Holt (1991) added integrity as a test to the traditional methods of testing naturalistic inquiry including the following: credibility, transferability, dependability of

measure, and conformability. Holt explicated the 10 techniques recommended by Belk et al.: (a) prolonged engagement and persistent observations, (b) use of triangulation with different researchers for data collection and interpretation, (c) frequent on-site team interaction, (d) negative case analysis, (e) peer debriefing, (f) member checking, (g) limiting exceptions, (h) purposeful sampling, (i) reflexive journals, and (j) independent audits. Neuman (2011) advocated applying similar criteria to those recommended by Belk et al.

Bernard and Ryan (2003) outlined eight observational techniques and four manipulative techniques for unbiased theme development. Shepherd and Rentz (1990) provided steps "to minimize the subjectivity of coders" (p. 62). Brent and Slusarz (2003) recommended computer assistance "to assess and improve the reliability of coding by the researcher" (p. 299). Last, Zelik, Patterson, and Woods (2010) proposed a rigor analysis model with eight specific components to establish rigor and prevent shallow analysis in qualitative research. In this study, I considered the discussion and advice of investigators cited above. These elements might also enhance the external validity of subsequent similar, but not necessarily identical studies.

Transition and Summary

The objectives of Section 2 were to justify and explicate design and methods of this research study. Critical to the success of this study was the careful and excellent execution of this plan. As a result, I can report meaningful, reliable, and valid results important to the general and specific business problems articulated in this study. In the following section, Section 3, I present study findings, outcomes, and conclusions.

Section 3: Application to Professional Practice and Implications for Change

In this section, I provide a review, examples, analysis of information, and outcomes from gathered data to research questions elicited during semistructured, face-to-face interviews with 20 physicians in Kentucky (16), Indiana (2), and Tennessee (2). The physician subjects included 16 males, four females, 18 of whom were medical doctors (MDs) and two of whom were doctors of osteopathy (DOs). Physician practice experience ranged from one to 38 years.

Overview of Study

The purpose of this phenomenological research study was to improve n-3 marketers' understanding of how physicians reach decisions to prescribe or recommend products including omega-3 (n-3) dietary supplements and which product characteristics may be the most important to physicians. I explored physicians'n-3 dietary supplement knowledge and decision criteria (ladder of inference; Argyris, 1976), and found physicians' inference ladders for prescription drugs are similar to physicians' inference ladders for n-3s. Argyris's ladder of inference model facilitates constructing a hierarchical schema to facilitate understanding physicians' decisions, ideal for the physician context because higher ladder rungs are not accessible in the absence of bottom ladder rungs. With physicians, as expected, the bottom ladder rungs are drug or dietary supplement safety and efficacy. After establishing efficacy and safety, physicians consider a number of other important factors (i.e., ascending ladder rungs) such as cost and reimbursement, their own patient experiences and outcomes, peers (especially specialists), performance and behaviors exhibited by pharmaceutical representatives,

supply of samples, direct-to-consumer advertising, and personal experiences of patients or themselves taking the products.

I interviewed the 20 physicians in private settings conducive to few interruptions. After concise introductions and *Informed Consent* completion, I outlined the interview plan, asked questions, and closed the interviews by thanking the physicians and asking for their follow-up response to an e-mail containing confidential transcript and them information. Following interview transcript review and study, I developed codes and themes in accordance with the code and theme development methods advocated by Meek (2003) and Li and Yeo (2011). Meek recommended reading and rereading transcripts, and then taking time away from transcribed manuscripts to contemplate coding and thematic development. I also enlisted the help of a second coder (IRB approved) to fulfill the intercoding verification process advocated by Li and Yeo and further validate the triangulation process advocated by Golafshani (2003).

Bertolotti and Tagliaventi (2007) emphasized the importance of data analysis objectification, a critical element to support study validity. Following the recommendations of Berolotti and Tagliaventi, I used intercoder agreement, peer review, and member checking to triangulate and confirm data accuracy and theme development. I e-mailed physician subjects their own confidential transcript content to ensure accuracy of transcribed content and thematic confirmation. One-half of physician subjects responded and of those who responded, all confirmed content accuracy without recommending revisions. I also engaged the help of a colleague in peer review. To ensure data accuracy, I audio-recorded the 20 interviews without electronic device glitches.

By rereading and contemplating content, I developed groups of data using codes, developed themes from codes, and reduced too many themes into fewer pragmatic themes and synthesized my analysis and conclusions. I evaluated my conclusions for prospective limitations and delimitations, identified implications for social change, made recommendations for follow-up study, and revealed introspective growth perceptions from the experience. This process was holistic and my research and evaluation methods integrated the problem statement, purpose statement, research question, conceptual framework, nature of the study, qualitative design, literature review content, validity and reliability controls originally presented in Sections 1 and 2.

The study outcomes enabled me to answer the primary research question: For the purpose of marketing strategy, what is the ladder of inference physicians use to recommend n-3 dietary supplements? To answer this primary research question, I first established context. Context included how physicians determine what drugs they will prescribe and what supplements they recommend because these decisions follow the same hierarchy of decision logic: patient safety, product efficacy, experience, cost, and other influencers. Physician decision logic fits ladder of inference theory (Argyris, 1976) with respect to specific decision influence components including the following key rungs in the ladder of inference: data selection (determining clinical trial credibility), data interpretation (how the data fit personal experience), practical and ethical factors to determine if assimilated data will change behavior (the action of prescribing or recommending products including n-3s).

Presentation of the Findings

Through a process of repeated and prolonged data analysis, I determined eight prevalent themes from this study. The first three themes were Theme 1: Clinical Trial Rigor, Practice Relevancy, Degree of Influence, Theme 2: Physicians' Experience and the Test of Time Determine Prescribing Habits, and Theme 3: Cost is an Important Influencer, Providing Competitive Products Have Similar Efficacy and Safety. Themes 4-6 included Theme 4: Peer Opinions Influence Prescribing Decisions If Peers are Specialists, Theme 5: Competent and Incompetent Pharmaceutical Representatives Have Antithetical Effects Influencing Physicians' Prescribing Decisions, and Theme 6: Samples Are a Valuable Influencer to Some Physicians.

The final two themes were Theme 7: Most Physicians Have Negative Opinions Regarding the Influence of Direct-to-Consumer (DTC) Advertising but DTC Increases Product Awareness, and Theme 8: Lost Influencer Opportunities: Physicians Need More Dietary Supplement Education and Lack of Dietary Supplement Curricula in Medical Schools. All themes are relevant to the core research question. Themes 1, 2, and 3 seemed essential as influencers and more important than Themes 4, 5, 6, 7, and 8. In the following subsection, I explain these themes in more detail and support themes with transcript excerpts. I also discuss the pragmatic applications of these themes to pharmaceutical and n-3 marketers.

Theme 1: Clinical Trial Rigor, Practice Relevancy, Degree of Influence

The following excerpts support clinical trial validity and reliability criteria physicians value to determine rigor. Important clinical trial methods include double-

blind, randomized, placebo-controlled, and number of subjects (sample size). Other important factors to determine rigor include investigator credentials and the reputation of the publication journal. Physicians also evaluate the relevancy of clinical trials including study venue, study subjects, and outcomes. In the transcript excerpts below, I protect physician anonymity by using an initial (e.g., Dr. H) not necessarily representing any part of the physician's real name.

First, Dr. H commented, "Very simple, number of people in the study. If it's 150 people doesn't tell me anything, if it's 5,000 people for 5 years, that's the first thing I look at," while Dr. T stated that, "Well how many people are in those studies? Is it a good one, is the finding statistically significant. I look for *p* values and study rigor." Other doctors commented:

> Is it effective, how many people, what are the risks, that's big for me because we cause a lot of problems maybe more than we solve, and I am very in tuned to that. Generally where I get my information, they are only putting in their stuff that is credible, statistically significant. I use *Prescriber's Letter*, I love *Prescriber's Letter*. I read *The Medical Letter*. I read something called *Core Content Review*, which is basically Cochran-based, that is where I get all my information, basically. (Dr. O)
>
> If I am looking, I want to know it's a large enough study, well done study, placebo-controlled, double-blind, that kind of thing. I want to make sure the conclusions drawn are what I shown in the study. You know a lot of times people try to draw conclusions for example 2 + 2 =4 therefore 4 +2 = 6, well you didn't

include that as part of your study so you can't say that, you know… a lot of the information the drug companies put out, it's not real hard data. In fact I'd rather get the data from an academic environment. (Dr. R)

Well, it's the number of patients for example if you are looking at a study with 10 people versus 10,000 people, the one with 10,000 will be more meaningful, number one. Number two it's gonna be how long has the product been on the market, do we have any bad reports, any recalls, FDA have any black box warnings. (Dr. I)

I look for the size of the study, how many subjects are involved, what kind of study is it, is it observational, is it placebo-controlled, who did the study, whether it is university based, Institute of Health based, or pharmaceutical based study, um, that's what I look for when I read articles. (Dr. N)

Dr. S stated: "OK, Is it a large enough sample? Are they measuring something important? Is it something definitive or is it something we are hopeful will work and we are not quite sure? Either the data is soft or we don't know the side effects" while Dr. G remarked, "Population size is critical. 20 patients vs. 400? Primary care docs don't necessarily look at raw data. At least they don't have the time to do that and don't have the time to do it. Look at how long drug has been on the market and credibility of company and investigator."

Dr. C stated: "Well basically, the ones who have a significant endpoint -- whatever they are testing for…reduce triglycerides or whatever…and that it works, and something that is safe. And always, what is cost-effective, more than anything." Dr. K

disclosed: “I look at how they chose the study participants and whether or not it would apply broadly.”Dr. B added: “Oh right, well obviously the source of the information has a lot to do with it, how big the study is also has a lot to do with it.” Another physician added:

> Double-blinded studies, multi-center, the source has a lot to do with it…What drives me crazy with some of these studies...they come up with these crazy scales…so the study show X was better than Y on some allergy retro scale…on some crazy scale and you say ours was .8 and theirs was .6 and okay here’s the difference between those two. A 30% difference on a scale does not mean a 30% difference on what I see on my patients. And on some of these depression scales it does not give you a point of relevance and so you say I don’t know how sick a .6 is and I don’t know how much better a .8 is, does it apply, does it make my patients better. So I think a lot of these studies give you information you cannot use. If you are treating shingles, I want to know how fast my patients will get better. I am not interested I splitting minutia that doesn’t matter in real life, or when *p* values are such borderline and they give you scores, those drive me crazy. (Dr. W)

Dr. A stated: “If the drug was tried on a few or hundreds of patients. Also if drug versus another drug with better results this is important to assess… The main thing is to read good journals, *New England Journal of Medicine, JAMA*…” while Dr. L advised: “And randomized, placebo-controlled…and you like to see more than one study.” Dr. E

remarked: “I know what the efficacy of the drug is. I want to know what kind of patients they are and I want to know how they compare to their peers.” Other physicians stated:

> Usually I look at several things, I look at, well the younger guys are much more analytical about studies but I am going to look at whether or not it is a blinded study. I look at the total number of people in the trial, so often we forget about even though a *New England Journal of Medicine* study, it has a total of 36 participants. I like a study that probably has more people. Is it 13 patients or 13,000? Who did it? Which centers? And then, applicability is a big thing for us, meaning did they do the study on 5,000 people from Tazmania? Really doesn’t have anything to do with my patient population. And so they can have great studies with great things but really doesn’t apply to me. So I think it’s important to look at all of it and see if it’s applicable…You can rely more on a study that came out of *New England Journal* and you expect studies to be credible...doesn’t always have to be that way but usually is. (Dr. J)

> I like a multisite study, I like more investigators than one investigator’s bias. And I like double-blinded because neither the investigator nor the patient knows what they are getting, or what they are giving. Those are the kinds of things I look at in clinical trials, multi-site, double-blind, big numbers. Sometimes the journals that are peer-reviewed will only allow certain studies. You’re going to have the top ten journals, or the top five journals and then the next 10. The studies are going to be more sophisticated depending upon where you look. (Dr. V)

> The top five journals have their pick and they are going to make you revise and re-submit. And I am going to go towards a more sophisticated study. With throw-away journals, I might not consider the study. And then I guess the one thing I really look at, in our academy, is the Cochran library, where they take all of the studies of a particular thing, and group them together. So there are positive studies, negative studies, and neutral studies and somehow they combine the numbers and make a recommendation based upon all the studies they could find in the literature. (Dr. J)

Theme 2: Physicians' Experience and the Test of Time Determine Prescribing Habits

In a relevant quantitative study (n = 135), Tichelaar et al. (2010) noted practicing physicians reach their prescribing decisions heuristically and may not be conscious of their own drug choice logic or value judgments. Tichelaar et al. noted unlike diagnostic reasoning, which is well documented in the literature, little is known about therapeutic reasoning (i.e., the decision process physicians use to make treatment choices). The findings in this study add understanding of the heuristic physician decision process of data selection, interpretation, assimilation, and action.

The selection and assimilation of data by physicians is a perpetual process. Clinical trial outcomes are important but in long-term effects on prescribing habits, only if physicians' personal experiences support those outcomes. All 20 physicians expressed reservations about prescribing unfamiliar products or new products on the market and most physicians described cautious approaches regarding new product trials. With

positive feedback and experience, physicians gradually increased product use. Clearly, regardless of physician decision influencers, the long-term trump criterion is their personal and patient-specific experiences. The following evidentiary excerpts provide more insight regarding these findings:

> No, I think it has to do with experience of practicing 34 years. You get somewhat in a routine. If you have a patient who you know a drug will work, you throw in tolerance and cost, you develop a comfort zone and you may add a new drug from time to time. But you kinda know with Miss Jones, these other products worked, so will this one. But you get into a routine using drugs that work and really don't try many new things. (Dr. G)

> If you ask me, and this is just me, we are all a little different, the single biggest thing to impact me has got to be familiarity. I'm not one that, as soon as a product comes out on the market I'm on it. I tend to take my time, use samples, evaluate closely. If they need an antibiotic for a certain indication, I tend to go with the one I know works. I know these are the downsides, these are the upsides, can't use it with that…familiarity is probably the biggest factor for me. And if something new on the market comes out and does not have that downside, I will start trying it slowly and carefully. But for me the biggest part is familiarity. (Dr. V)

The physicians expressed strong opinions regarding their direct experiences with drugs and supplements, especially new products. Dr. I stated: "Everybody has their own experiences and own opinions. I would get more influence by the patient themselves. Somebody says I tried this and it helped me, I would go for it even though I haven't had

much experience" Dr. H added: "Now with new drugs I got burned so many times, a new drug comes out, any kind of total new drug, I sit around and let somebody else use it for 4-6 months." Dr. N stated: "Yeah, have been burned before about drugs that have come out, even for 5 or 10 years, and then we found out, so we've all been burned." Dr. M admitted: "I tend to trust old friends who are not going to mislead me."

Adding to the importance of product experience, Dr. S stated: "With some new products I don't feel secure enough that it's been out long enough and that there is enough people that have been on it." Dr. K revealed: "I want to be familiar with the drug and I want to know it's mechanism of action." Adding a comment regarding proof of product efficacy Dr. C advised: "Something like omega-3 I can draw blood and show someone cholesterol levels and the test the same later, maybe 3 months or 6 months later to see/show results. Those are the kind of results that open eyeballs." Other important physician comments:

> I am very influenced by the big trials, like the nurses trial on breast cancer, and the big trials on hypertension, what drug over the long haul always comes out on top. Like you can't beat ACE inhibitors. You cannot beat hydrochlorothiazide. It prevents more heart failure than anything else and it has been out for 30 years. I guess that's the big one for me. (Dr. O)
>
> Something that is very new, I might be a little skeptical before I use it. Um, and the thing is, most medications are not new. If you go and look they are in Europe 10 years before they are here. In Europe they are much faster. They give the OK to go out on the market much faster than FDA does here. So if I see a medication

> that has been on the market for 10 years in Europe but now it is here, I will go for it. Something very new, experimental, maybe I will wait a bit to see what's going down the pike. (Dr. I)

Theme 3: Cost is an Important Influencer, Providing Competitive Products Have Similar Efficacy and Safety

One surprise in this study was the emphasis and importance of cost as an influencer of physicians' decisions to prescribe drugs or recommend dietary supplements. Without exception, physicians expressed frustration with inordinate product costs and provided compelling patient experience examples where patients did not comply with physician directions because costs were too high, even if patients knew health consequences would result from noncompliance. Based upon physician explanations, in the physician ladder schema of influencers cost elevated to a primary decision influencer as perhaps the third most important ladder rung after credible clinical data and physician personal experience. The following transcript excerpts enhance the prominence of cost in the overall physician decision-criteria hierarchy:

> That is the top priority. You know if you have patients who are Medicare or who cannot afford the drug you are not going to use it. So that is a major issue. And sometimes you have to acquiesce and choose a less expensive drug even when you prefer the brand or they won't be able to afford it and flat out won't take it. (Dr. G)

> [Cost] Big, big. Not for me, but for the patient. Even if the clinical trial outcome is phenomenal, I can think of a hundred medicines, amazing, look at the reduction

> in systolic and diastolic blood pressure – the results may be amazing – but if that medicine costs the patient a hundred dollars a month, the patient is not going to take it. You have to be practical. (Dr. D)
>
> I think from a patient's standpoint, the economy of the drug plays a far bigger part than you guys realize. I have reps in here all the time and I say really, if you would have priced this at $40, I would have 2,000 patients on it. At $140, three. And you can't tell me it costs $120 to make this stuff because it has been out forever. And they say well we evaluated it and if it saves one hospitalization a year it saves this much and I say don't give me that crap my patients aren't paying it. These new diabetic drugs are now $300/month versus the old sulfonamides for $20 that work just as well…But I think patients are more cost conscious than ever. When formularies were $5, $10 and $15, who cares. When $5, $50, and $100, wait a minute what is all this formulary stuff. Well you had it all the time they just jumped it. (Dr. W)

Physician expressed strong opinions regarding costs. Dr. M stated: "Yes, it's a big factor. More than it used to be because things weren't as expensive back then. They're all expensive now…People are really concerned about cost…as long as quality is good then you're going to look at cost." Dr. F prioritized decision criteria: "Safe, effective, available, and cost… Cost is way up there, very important." Dr. V added: "But we want everything covered by our health insurance and then don't understand why it goes up every year…is criminal in what they charge people and keep raising prices higher and higher." Physicians explained why cost is so important in the following longer excerpts:

And I'd go down to the Braves game and the box down there and when I finished my talk, I'd say after all this stuff, be honest with me, what is the single factor that will get you to write a drug, and every stinkin' time it was cost… Yes sir, that's the single most important factor… and they came to me and I said I know what I am supposed to say, I'm supposed to say efficacy and safety and all that, I said, it's cost. I'll just tell you it's cost. And the guy next to me, he started, and he said, he's right. And the guy before me said, an internist from Mississippi, said I want to change mine, he's right, it's cost. Every one of them said cost…But pharmaceutical companies don't get that. They say well if we cut the price then they'll cut the price and we'll get into a price war. But if you make a good product at a good price, doctors will use it. They'll lie to you and tell you it's something else but I'll tell you, it's cost. (Dr. H)

It's pretty high for me, unfortunately, but cost is very important. Regarding brand names they are more expensive but if there is a tried-and-proven generic, I usually go with that one first. And if they don't do well on the medication then I will go to the brand name. Unless it's something that is not good enough in my mind in that class of generic drugs, then I will go to a brand name. (Dr. P)

All these things play a role although sometimes you still feel even though it has a black box warning, you have used this product for so long, so good to the patients, so you pretty much put that aside and go with your gut feeling. Um, insurance, if it's covered or not, it's significant. People these days they don't want to pay a penny over what their insurance covers… They say "Well, I have insurance" but

you know, it doesn't work that way. So I should tell them now it's gonna be $200 co-pay, going up and up and they say, forget it, I don't want it. Doesn't matter if it's a life- saving medication, doesn't matter, they won't go for it… I think it's also the fact…20 years ago, only one or two medications were expensive out of the whole realm of drugs. Today, some medications are 400 or 500 bucks. They are routine, so that has made people skeptical about anything not covered by insurance. (Dr. I)

Nowadays pretty huge cause patients are pretty savvy about that. They call you back and say, "Isn't there a $4 choice or generic for this? This costs too much." So you have to factor in cost a lot because if you keep writing people $70 medications they quit seeing you. It is that world now and they won't come back…in my parents day their copay was $5 bucks. Now a third-tier copay is $50 or $60 dollar copay and somebody tells you there is a $4 cholesterol medication on the list at Wal-Mart. So people are savvy enough to be looking at that and saying isn't there a cheaper alternative I could be taking. (Dr. T)

Around here we see a lot of people who do not have insurance or who have very poor insurance. Ah, we see a lot of people who are cash pay, people who have a very high deductible and it won't pay anything until they hit say $5,000 in medical bills. So in those cases cost is a huge factor. I can give them something but if they won't go fill it, it doesn't work. Or they just get mad at you, one of the two. But more of the time they just don't get it. I saw a patient yesterday and she had a really bad cut on her finger and she went to the ER and got sewn up. I gave

her an antibiotic. She didn't get it filled. Now it's a big, nasty infected wound. This was something she needed but she couldn't afford it. So cost is a big issue especially, if well if you take something like an antibiotic and you are on it once that is one issue. But if you are taking something for the rest of your life, cost is a big, big issue. (Dr. B)

Huge! I am a generic user, a big, big, generic user. With drugs, if it hasn't been in our magic sample closet for at least a year, I am not going to use it. Sometimes with cardiac drugs I will use it if I know a lot of cardiologists have used it and I have spoken with one I know who is conservative and they say yeah I am having a lot of good luck with this drug. Antidepressants, no way. Cholesterol medicine there really isn't that much that comes out. And diabetic medicine, I may be more apt to try that. (Dr. O)

Well, when I prescribe things, I am simultaneously thinking of several different things. Efficacy and how the drug will work, cost and their co-pay status, how it fits, ease to take it, side effect profile, I am thinking of all these things at the same time. (Dr. R)

It's important to me because 50% of my patients are cash pay. They don't have Medicaid, Medicare, or private insurance. So it's important because what they have to pay is going to determine whether they are compliant whether they are going to take it, whether they are going to take it past what I give them. I may give them a sample. But if they can't afford and they are not going to buy it, it's simple. (Dr. E)

Um, I don't have to know it's going to work on that individual but I have to know it fits the individual's lifestyle. Is this person going to be able to afford what I choose? Is this person one who will feel comfortable taking something that is not a prescription? Is this an expensive prescription? A lot of it is financial state. Of course, if I believe it can help them, and they really need the more expensive medicine, I will encourage them to really make a sacrifice for it. If I am uncertain about it, I am going to have a lot of trouble trying to convince them to take something I don't necessarily believe in. [If I prescribe something too expensive] They don't take anything or you get a callback in a day or so saying we can't afford this. Is there something else we can take? It is a terrible feeling in a day that you gave someone something that was impossible to do, was a failure, and you shouldn't have done it. [Pharmaceutical companies] Yes, they really don't factor that in very well. And they don't think about how much these people are taking. And if they are Medicare, they are even more vulnerable to those problems. If they have insurance there is a hope. If they don't have insurance they are dead in the water.

Medicare, maybe will cover, maybe it won't. Insurance, maybe will cover and maybe it won't. Uninsured people, forget it. And then they hit the donut hole and they come in and say, "I can't afford this for the next 3-4 months" so then we gotta figure out what to do to get them through the donut hole. So there we have double work. All of sudden we had a medicine I wanted to count on for a year and I can't count on it for a year. We have to change the script, somebody has to

input that data into our computer system and then the patient has to bring the bottles in so we can confirm what they are taking and make they are right. And this just doubles our work in a year's time with a prescription list. (Dr. R)

Yes that is the other one I was going to get to. Interestingly they pulled quinine off the market which is the old standby that was used for ever, and it costs pennies, and as soon as they pulled quinine suddenly we are putting people on anti-epileptic medicine costing three figures, hundreds of dollars to put them on this stuff, you gotta titrate it, you gotta be careful. And all of a sudden what we used to use and treat for pennies, now we are treating for hundreds. Well, older people, a lot on Medicare, and that donut hole becomes huge to many people. It's just half a year and I already have patients hitting their donut hole. And now they have to float the whole cost of medication because even if you have an over the counter it's better than Lovaza...that pushes you towards your donut hole. So by the 6th month, you've spent $500 towards your donut hole whereas if you bought the over the counter version which is about the same as your copay, you've spent the same but don't have it going towards your donut hole. That's a critical factor.…I've gotta have the price and the efficacy to match. If it's something that's very expensive like a cancer drug, then it's something you can't do without. When you're talking about BP medicine, I can give you a $4 medicine that is going to work great, why would I write a $200 medicine because a drug rep told me to? By the same token if I am using, for instance I believe in Synthroid, versus a generic thyroid medication because it's so important to keep your patient

> balanced. So cost enters into it, but then there are some drugs worth it. And I think that is probably what does it for me. I‘ve gotta look at cost and sometimes I don’t have a choice. Well you’ve made me think about why I use the things I do. I don’t know, ease of use, cost, what the patient will use. Because I always tell my students, you can write any damn thing you want, but if the patient doesn’t take it, you’ve done no good. You gotta read your patient. I have patients all the time call back I can’t afford it I can’t afford it. You stay at this long enough and you learn what works. I don’t want those callbacks and I want to know it’s going to work right up front. (Dr. J)

Theme 4: Peer Opinions Influence Prescribing Decisions If Peers are Specialists

I classify credible clinical proof, personal experience, and cost as essential influencers. Other influencers may be important as well but may vary in their degree of impact, depending upon physician individuality and preferences. The influences of peers, pharmaceutical reps, DTC advertising, samples, and dietary supplement education (or lack thereof) may all have some influence, but to varying degrees depending upon the physician person. Not surprising, younger physicians seemed more receptive to peer influence than did more experienced physicians. The following transcript excerpts provide insight regarding the variability of physician peer influence:

Peer influence may be most important with new medicines. Dr. L stated: “Peer experience is important especially with new medicines.” Dr. F was positive regarding peer influence: “It seems to work out better when I take the influence of my peers first.

They give me specific instruction on how they have used it. If they say it works better, it gives me a motive to try it." Dr. O disclosed: "Yes and you get information when you send a consult to someone and they send you back a report. I like to read my consults all the time." Dr. K clarified: "More if a peer feels comfortable using a medicine as opposed to the horror stories of medicines."

Younger physicians may be more receptive to peer influence. For example, Dr. M stated: "Certainly influenced me in residency when I was learning things. Don't have that contact now. But we share with each other so yeah, we have some contact. I still listen." Dr. P remarked: "Peer influence…residency yes. We get into the habit of using meds and then it's hard to break me of the habit. "Conversely, a physician in practice for many years, Dr. I remarked: "Not really, everybody has their own experiences and own opinions. I would get more influence by the patients themselves…But not what other doctors say or think. "Physicians added other insights regarding peer influence:

> If there is somebody in my immediate circle like in this group here…for example if Dr. R has been using a medication and I see his patients get good response, if I have not been using it, I might start picking that up. Usually I am one of the slower first adopters of new medications and if others want to try it first that is fine with me. I will wait and if there are no problems, I might start picking it up. I'm a fairly slow adopter when it comes to that. (Dr. N)
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> I find that medicine has become the complete opposite of what we ascribe to here . . . we try to communicate, we make calls, we send complete records, we try to do everything we can so subspecialists know all they need to know. And for the

most part medicine is pulling apart so we don't have as much collaboration as we used to. Having said that, If I talk to somebody and my pulmonologist tells me this is the best metered-dose inhaler because of this, that, and the other, sure I will use that information…he sees the troubled cases. Subspecialists, now when you are talking about that kind of collaboration I love to learn from those guys. They see the trouble cases. While we see a boatload of them, we send them the ones we can't fix. (Dr. V)

Probably for certain specialty drugs I am certainly more influenced or more apt to use something if the allergist I use all the time prescribes it…I probably do get some comfort with a med when the patient comes in and the cardiologist has them on it and I get a little more knowledge about what it is because patients are already on it. (Dr. T)

Yes I look at what the specialists prescribe. For example if I send patients to a cardiologist and they always come back on a particular drug, I get familiar with that because I know if I am going to use a different drug the consultant is probably going to change it. So a consultant has an influence on me. (Dr. J)

[Peer influence]…me particularly, not too much. 'Cause I don't have a lot of interaction with peers anymore, other than the partners in my own office. I did more of that when I did hospital rounds. We'd sit around with specialists in the doctors' lounge and discuss drugs. We no longer have that opportunity. Non-hospital doctors no longer have the kinds of meetings except when a pharmaceutical company sponsors a symposium to present their drugs. (Dr. G)

> Yes we used to have roundtable sponsored by drug companies…we used to do it. But we haven't done one it 10 years . . . $50 for a dinner . . . takes time. But I think it's a good idea, you get the doctors together, buy them dinner, pay them for their time, and let them discuss the drug and the best way to use it. I think that is a good idea. That was when we got the most useful information because we shared with each other our experiences and did not rely on research conducted by the industry. This is a good idea. It's not that we are coming for the dinner, we are coming for the information. But when you look at it, all the drug companies have gone to marketing nurse practitioners, not the doctors or taking them out to roundtable dinner. That was the best system we had. (Dr. A)

Theme 5: Competent and Incompetent Pharmaceutical Representatives Have Antithetical Effects Influencing Physicians' Prescribing Decisions

In a relevant retrospective study Joyce, Carrera, Goldman, and Sood (2011) noted physicians regarded pharmaceutical representative detailing as an important source of information. This study's results support the findings of Joyce et al. but add understanding regarding the type and degree of influence – positive or negative – depending upon the skills of the pharmaceutical representative and resultant physician's receptivity to individual representatives. Regardless of company or product, physicians expressed strong and consistent opinions, the most vehement of all responses to interview questions in this study regarding the behaviors and skills of pharmaceutical representatives. Perhaps one reason for this stems from the dynamics of interpersonal relations and some pharmaceutical representatives' blatant disregard for the value of

physicians' time, lack of discernment, poor judgments in physician offices, deficiency in identifying customer needs or embracing a customer service orientation, poor product knowledge, high pressure tactics, and failure to deliver concise, valuable information physicians can use to augment quality care.

Physicians also commented consistently regarding the counter-productivity of company managers when accompanying pharmaceutical representatives. Physicians noted the inappropriateness, redundancy, and superfluity of representatives' comments when accompanied by managers, almost as if they must follow a predetermined script written by corporate or field management authors seemingly out of touch with the real-world needs of their physician customers. The following excerpts depict physician subjects' passion and may enlighten understanding of these findings:

> People who are so bought-in to their data they are not going to even look at the other alternatives as viable options. That just completely turns me off. If someone says "our medicine is good and we understand there are other good ones out there, here is what sets us apart. These are the side effects to watch for." But when they start saying "you shouldn't use this or that because you should be using mine, then I think they drank the Kool-Aid." (Dr. L)
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> Ahh, the people I abhor are the ones who are so doggone aggressive. And no matter if they see you sweating and people screaming, they gotta tell you every study and the outcomes and just my pet peeve. And most of the time I just let them finish but there have been a few times when I have not. But for the most part, the ones who come in, now if it's the first time I want to hear what they have

to say but the ones who come around regularly, and say the same thing, I told this one guy you just can't be that pushy, go push someone else.

And I want to be treated the same way I treat them. Let someone come in and tell me about their product, leave samples, see how I am doing…that's what I want. Most of the reps have made that adjustment. Unless they bring their supervisors with them and they have to make the points and I have to sit there and listen to them. It's a game. And they ask me what if I bring my supervisor with me and that's what they do. (Dr. C)

Well I am pretty opinionated on this and I don't want to step on anybody's toes and the only representative I have ever met from your company is ideal. OK, I will tell you what turns me off, don't ask me about my kids, don't tell me I have cute shoes on. I despise that. Don't try to kiss up. At all. Hate that. But give me real information, and I don't want studies with 365 people, give me the down and dirty and I will listen. But if you've already stood there and talked to me for three minutes, which is three minutes I am supposed to be with patients, I am not going to be able to ask questions about what I really want to know. And I want to know the difference between the competing drugs, say, "Well the biggest difference between these two drugs…what my drug does versus what their drug does"…Now this may not be possible because they may not know what the AstraZeneca drug does or what the rep is saying. But it would be nice. The facts. And big glossy pictures, no. Now if you've got one page that summarizes, OK.

But if you have to turn 4-5 pages, no, my eyes are glassed over and I'm thinking about my next patient. (Dr. O)

Drug reps are good resources but the information is about their product but the information is biased and not objective… The one thing is the good reps are concerned about patient care. The worst ones are the reps that disregard the cost of their drug and whether or not people can afford it. (Dr. F)

The best drug rep I will tell you, he is the best rep, he knows everything about his drug. He will bring in a clinical trial with highlights and quickly point out all the things I need to know. He knows everything. He knows what his competitors are doing and what the benefits of each drug are, he is so into it. But some reps I will ask them even the basic information and they don't know. (Dr. D)

I think pharmaceutical reps that have new drugs, that is one thing they can really do, they can hone in and give you clinical information about the drug to help you decide . . . I haven't run across many who I would consider "bad reps." You know, most of them respect your time, are concise in their delivery of information, and I like the reps who are knowledgeable about their products and if you ask them a question and they don't know the answer, they will get back to you. (Dr. G)

The biggest thing for me is when you have a new product, I want to hear from you. I want to hear clinical data. I want to see studies. You know after you've seen them five times and you keep hearing the same stuff over and over again, at that point, if there is an update, you want to hear something short and sweet. If it's

something new and I ask questions on it, I'll expect a longer answer. If it's a drug that's been out for five years, you don't expect a lot of new information on it and you don't want to sit there and listen to the whole thing.

I am much more receptive and I think they do a better job when the manager is not with them. They are trying to hit bullet points and I understand and I'll sit there and listen to it and I know they are doing it for their boss and I'll sit there and listen to it. But honestly, they are not as effective as when they are alone and they can relate to me on a personal level and give me the information I am looking for. The best drug reps know you and how you work and know the kinds of things you want to hear from. You know they'll talk to you on a personal level and they will make their bullet points they need to make. When they hammer on you, it gets the opposite effect of what they want because they are pushing on you. (Dr. B)

To me, they are a good informational source, biased of course, but for me, I temper that. And If I am speaking with someone who is unfairly biased, I can also speak my mind as to why I don't like the drug. Some of these reps coming through and I tell them this is a horrible product. I have actually told some reps they need to look for another job. I have told them this is a drug that is going nowhere and you better go somewhere where you are going to be employed for awhile. I would think the most important thing is to establish a relationship, has nothing to do with their product, has to do with the relationship. Say, "I know you are busy today." Say, "I know you are busy today and I won't take much of your

time." Then don't take much of their time. Say, "Is there anything you are uncertain about with this product I can help you with?" And say, "I can come back later if you don't have much time." Any offer to make the doctor's day go better. (Dr. S)

And usually the best drug reps are the ones you become friendly with and know them. I had one rep who I finally refused to see her…she would quote me the same slogan every time I saw her. It became a real waste of my time to walk down the hall. She wouldn't say hi, I didn't know anything about her. I didn't know anything about her family and she knew nothing about me. I got the same words all the time. I think it's important they not be pushy, that turns a lot of doctors off. Also, don't like when they suggest why are you using that drug over another or gosh, why would you use that when you could use this one, that turns me off. I do remember one girl in the sample closet saying where are all these drugs going, we are not getting any scripts, what's happening here? Well we ended up kicking here out of the office; she was obnoxious. I don't understand all of the ins and outs of the pharmaceutical industry but these folks are professionals and I am sure they have quotas and have to sell so much of their drugs. So they have the tedious job of hitting their numbers and keeping the doctors happy at the same time. The best reps are the ones you can get to know a little bit, who are confident to me it shows they are confident in their product. That ok, I don't have to give you the same slogan all the time it speaks for itself. There's a lot to be said for that and it also shows there is real concern for you. Your busy, your running

like crazy and when the reps walk in the patients get ticked. And they really don't want me in the hallway spending a lot of time with reps. You know, a few of the better reps we invite back to the office. Back in the day which dates me how old I am, every company had one rep. And the rep came in and talked about all his products and he knew your family and you knew his family. But now face time became important and you have five reps for one product and the competitor has five reps and really, it's, it's a waste of our time. With so many reps coming in any more, I don't think you have to have 20 reps/day. We're either going to write the product or we are not. You just see where we are with it… The one girl, it got so bad, I told her, every time you give me your sales spiel, I will write your competitor's product three times. (Dr. J)

Well the ones that turn us off are the people who walk in and say will you commit to writing this many prescriptions in the next week? And the people that think their drug should be the first line drug and I just look at them and say well the generic drug out there is the first line and they look at me and say well you should make my drug first line. I say there is a good $4 generic equivalent out there that is a good drug. I am never going to use your drug as first line so continuing to use that as your sales pitch is not going to make me very happy. I think it more of, you know, the high pressure, and they say, "When I come back in here you will have written at least three prescriptions for this right?" No. (Laughing) You know this is a small office and it is just me and the ones who just want to come in and just chat…But I have a question, they don't have an answer and they need to go

look it up. The guys that say, “I see you are busy. I will check back with you”… they think of themselves more as a resource to me than someone that is trying to sell something to me. And I use them as a resource occasionally. “Have you been hearing of this side effect?” And they will tell me “yes” or “no” and what they have been hearing from other doctors. Well then they are useful and then there are days I am running around like a chicken without a head and its useful when the rep walks in and says, “It looks like you are busy and I will check back with you next week.” (Dr. T)

Don’t try to push too hard. Be subtle, give information, be educated. If the doctor wants to know more about the drug find out about it. I am finding a lot of drug reps do not know about their drug. I don’t care how good they are dressed up. They need to know their drug…Drug reps have a role to play but doctors don’t have a lot of time. I know they bring lunch and so forth but just because you spent $10 for something to eat doesn’t buy me anything. I think if the drug companies just spend money on drug reps to educate the doctors and not consumer advertising this is much better and will save money, instead of drug companies spending $500M on consumer advertising. The advertising costs much more than the drug. And the thing is it doesn’t matter, all of these drugs are the same. If the FDA wants to help, they should stop approving drugs that cost so much. I can prescribe prednisone for $4 but instead patients want drugs that cost $250 and don’t work any better. Supreme Court in India ruled on lowest cost drug. (Dr. A)

And it's more the big pharma reps who recite just like they were trained. Doctor, let me show you this brochure and they want to go through all 12 pages of studies which is great if it's new and a revolutionary product and if I have the time. But they are not going to vary from their presentation because that is what their boss told them to do and they finish with, Can I count on you for the next patient and I think really, we don't do this. I like the guy who comes in and says hey doc we just finished a study on X and if you are not too busy, let me show you the highlights. Not right now I don't have time. Great next time or may I leave it with you?...It's those reps who can vary their patterns who know if I am busy and they just need a signature and leave me alone until next time. That goes much farther than the person who says well I will wait, you go and see another patient and then we can talk. The ones that don't read the physicians, you get tired of them. You know we started in the old days when we had one Merck rep, one Lilly rep, one Boehringer rep, and you could count on that rep to take care of all of those products. And then they went through the phase when you'd have six Merck Reps, 5 Pfizer reps, 6 Lilly reps and you'd have six Merck reps in one day and you wouldn't know which product they were carrying. Gosh guys I don't have time for this. It's let me remind you about my product, here are the side effects, what can I do to help you, I would love to leave you samples, or what data can I get you, what can I do to help that's what you need. What's the cost of your drug for my patients who don't have insurance may be all I need to know. Yes and sometimes I just get a package insert but I need feedback on a drug, need some

true education on it from the rep. And it's almost a façade and I have to say are you really trying to help me here or not. Because I gotta figure out how to use this drug. Tell me how to use this product because it's not working for me this way and I need some true education about this product. (Dr. V)

Dr. L: "…[sometimes need them to] answer a formulary question."

Yes. The best rep is the one who will come here and talk to me, not just about what he sells, I want him to come and educate me. This is my product and it has this and this and this and this. And then there are other drugs on the market, similar to ours, but this is what ours does better. But if someone comes here and says all these other drugs are crap, don't even waste your time, this is the best you can prescribe, well, I would say this is the worst rep. (Dr. I)

Best rep, friendly, easy to talk to, has a drug that is actually helpful, I do feel sorry for reps who have drugs that are not very good – there are other drugs in the therapeutic category that are actually better. Usually one or two points are all I can really tolerate, one to remember but if it gets into 3 or 4 points I really don't have that much time, quick to the point, friendly, samples, one who have discount cards as well. Worst, ones who take too long or those who ask for a specific number of patients: "Maybe could you start one or two patients on this drug this month?" You know, the hard sell, that is really a big turn off for me. Just lay out the points, this is how many points this lowered cholesterol, this can really help you patients, that is much better. (Dr. N)

The only drug reps that are going to bother me are the ones who insist upon pushing the envelope. In other words, they know what the rules are, they know what they can do and what they can't. You don't have to be the brightest person in the world to understand that. If they interrupt me when I am in between patients and they see I am busy then I am going to be upset. So walk in the door and get it done whether you have samples or not. I don't particularly like it when people hold up brochures and go through them page by page. If they have one sheet and they want to make a point then make the point. In my opinion, what you need to do is be aware you are providing a service, not an advertisement. If you want to provide a service no one is going to give you a problem. If you walk in and say I have a new drug that may be of use to you and you give us the stats and be on your way, no one is going to have a problem with that. If you try to sell me on the same product and say the same thing over and over again, that is going to insult me. I got it three times ago. I like it when they come in and describe their product and tell what patients to use it on but not ask now what or how many patients are you going to prescribe. (Dr. E)

The best rep is knowledgeable about the disease process to begin with, and then knowledgeable about their product, has to be knowledgeable about their competitors. You know I lean more towards the one who has a scientific background, who can answer my questions on a scientific basis. And then give me the information when I want it and not try to give me all the information when I do not have time to receive it. I have one or two reps I cringe to see, who want to

> give me the full detail, when every room is full and they have no respect for my time. And I am just really not going to listen to anything they say. Whether they give the whole spiel or not. (Dr. R)
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> I like it when they come in and describe their product and tell what patients to use it on but not ask now what or how many patients are you going to prescribe. Right now if they say will you write this for the next 10 or 15 patients that will be the last time I talk to them. (Dr. M)
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> I like it when it appears they have some honesty about them and they are going to tell me what is in the clinical studies and so forth and they are not going to hide studies from me. I mean I know they all do it to some degree but I like to feel that if I answer a question I am going to get an honest answer. Usually I'll ask a question I know the answer to just to see what they say and if they are lying to me I won't listen to anything else they have to say. (Dr. K)

Theme 6: Samples Are a Valuable Influencer to Some Physicians

Drug sampling as an influencer was supported by Joyce, Carrera, Goldman, and Sood (2011), who noted pharmaceutical representatives' drug sampling provided greater flexibility for low-income patients as well as clinical experience for physicians. The findings of this study may complement the main tenets in the Joyce et al. (2011) study by providing information relevant to the changing health environment physicians are witnessing and will witness in coming years, catalyzed by new health care trends and regulations (i.e., Obamacare). Physician comments support the patient benefits afforded

by samples, but at the same time, acknowledge private and government payer pressures to prescribe more generics have resulted lower sample supplies.

Transcript excerpts provide more specificity regarding samples as a decision influencer. For example, Dr. L stated: “I prefer samples to coupons. Most of the time I don’t think patients take the coupons.” Dr. M advised: “To give good service, bring samples.” Other physicians explained their positions regarding samples thoroughly:

> [Samples are] Big, big. You see, I’ve been a physician 30 years, and in private practice 24-25 of those. And samples have always been huge. They can try the product and see what the toleration is before we start spending money. It has been an unfortunate lack in recent days. Everything seems to be generic. (Dr. R)
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> And I think that’s where samples help a ton. Give somebody two or three days and let them take it. Cause we’ve all seen it. You write them a script for $100 and they take one pill and they have a side effect and can’t do it. If I had given them that pill and they had the side effect I would have saved them $100. Or they could say gosh I love that stuff and can take it forever…A lot of times it depends how long they are going to be on it. An antibiotic, don’t give me two when I have to write a prescription for five more, that doesn’t do any of us any good. So at least give me a whole pack so I can give it to one patient today and then if it works I can write scripts for other patients because I got good feedback. Now with a longer term product give them a week’s worth of samples and usually they will fall in love with it. If it’s something like a statin drug where they are going to be it forever, that’s where the coupon comes in handy because they are going to be on

it for a long time. And you don't need three of these, you need two months' worth. So it varies. With acute type stuff it's different. And that's where the samples come in to make sure they are not going to turn green on the stuff after spending $50 for pills. Oh sure, the other problem with coupons…I think patients sometimes get pushed back from the pharmacists. I don't know how coupons work on that end but I get the impression from other physicians pharmacists get tired and don't want to fool with them. In some cases they turn the coupon into pharmacists and then pharmacists have to get the coupon to you and in some cases they say the pharmacist would not honor that. That's the only problem when the patient must present the coupon to the pharmacist. (Dr. W)

Practically speaking, there's not a lot of difference between those medications but what is the patient going to get? The one that is on my shelf. Because I can give it to them, they can try it, and they can see how they do. So that is the one thing that is out there that I think is the elephant in the room out there that pharmaceutical companies and drug reps do not see. The government says ahh you are making people spend more money. No I am not, I am helping people spend less money. I tell you what, you may not want to know this but what does affect what I use is what I have on my shelf. You know if I am looking at a diabetic medicine because I am dealing with a lot of people who pay cash money I will look at what I have on my shelf. (Dr. E)

Theme 7: Most Physicians Have Negative Opinions Regarding Direct-to-Consumer (DTC) Advertising but DTC Increases Product Awareness

The results of this study confirmed and expanded the findings of Frosch, Grande, Tarn, and Kravitz (2010), who examined proponent and opponent studies from peer-reviewed literature. Frosch et al. (2010) determined ads frequently did not disclose alternative treatments, risks, or costs, and prompted patients, many with insufficient education or understanding, to request physicians to prescribe an advertised drug, the same complaints voiced by physicians in this study. Frosch et al. also determined physicians may not have seen the advertisements for drugs patients requested or were not fully educated regarding new drugs at the time of patients' requests, ads increased requests for advertised drugs, and these situations predisposed conflict with the physician-patient relationship. This study differed from the Frosch et al. study with respect to approximately one-third of physician subjects who offered positive or neutral responses.

Categorically, physicians acknowledged DTC increased patient and physician awareness. One physician observed most DTC advertisers promote expensive products and therefore, demand for those products is tempered by patients' unaffordability. One physician opined DTC may increase patient visits and a few physicians stated DTC made his job easier because patients already accepted the prescribed product. Second to the physician emotion voiced over pharmaceutical representatives, physicians who opposed DTC expressed strong sentiment, evidenced by the following transcript excerpts:

I generally don't like it [DTC] especially TV commercials, and it's usually for conditions that are not life threatening, they are more lifestyle based…things like testosterone and bladder control agents things like that…Viagra…things that are not really important to the long-term health of the patient. Things like that irritate me. (Dr. N)

You know. I don't think it has as big of an impact now as it did when I first started. Because now all the stuff that is going direct to the consumer is more expensive. Cause the patients come to me and say I saw this commercial on TV and I should try Cymbalta and I say yeah you could try that and then they come back and say maybe I could find something cheaper. (Dr. T)

[DTC] has had its place, at times to bring a topic to people's awareness. And you could use testosterone as one of those issues but it has probably been for a greater percentage of the time, a detriment. Where people come in and they say I want that purple pill and they don't even have reflux, and what makes you think you need the purple pill? (Dr. R)

That is a big turnoff. Myself, we don't have TV, so I don't know what's on TV, so I don't see a lot of that stuff. But it's a turnoff when a patient comes in tells me they want it. But that doesn't mean I won't write it for them but it is annoying. (Dr. O)

To tell you the truth, I don't like it. I don't like it because the patient doesn't know the whole picture. They just see what the pharmaceutical company wants to tell them. I don't like it but on the other hand if this patient has a problem that can

be treated with no major side effects by taking this medication, because let's face it, part of the treatment is placebo. On everything, no matter what, people taking Echinacea or something like it, it helps with the flu. Well maybe, but a big percentage of people get better on their own, but the idea of taking something helps them get better. So if someone wants to take something and I don't see any major problems with side effects or interactions then I say take it, try it, and let's see what happens… Like osteoporosis, I took Evista for a few days and I feel stronger. Well you're not going to feel anything for at least a week (laughing) but I know the difference. It won't help you for at least a week but the patient says well I took Evista yesterday and I feel it in my bones, stronger. So I say if you want to take something for osteoporosis you might as well take Evista because you say it works. In that case I would go for it. (Dr. I)

Umm (sigh)…I think most physicians initially felt it was a bit insulting thinking they were taking power away from us but you have to be able to deal with it. You have to know patients are going to find out things on line. Normally the people come in and ask, and half of them are candidates and half of them aren't even close. So uh, the big one now is Low-T, the low testosterone. Number one, was that created by drug companies? Is that a real issue or one created by drug companies? Low testosterone, there are still physicians who believe the issue was created by drug companies to sell their drug. So I think most physicians are a little leery of the big pharma anymore. They are more leery and they don't believe everything. But we have patients coming in asking but then you step back and you

go, but you know what it generates patient visits. Maybe it isn't all that bad, maybe we are all in this together. But they stuff they direct market to patients I would say about ½ really need what they come in and ask for. (Dr. J)

It changed things so dramatically in our world from the standpoint…you have to ready to deal with it. Both the good and the bad of it. You now that they are a little more informed. If it's not I saw it on TV then it's one of their friends, so we have to deal with this stuff all the time. And everybody in our practice knows somebody, and that person told them they oughtta talk about this…I think it impacts us…I don't think it sways me enough to say oh yes, you definitely need to be on that, now, if it's a toss-up between two or three things I will say, I don't have a problem with that. I won't put somebody on it just because they say they want to be on it…So you are trying to stay as much as you can off the radar with the news so you know they are not reading 8 million things about it every day. If they hear a negative story they are going to want to stop it immediately and if they hear about side effects they will be pre-programmed to experience those side effects. (Dr. V)

Um, it has its place. Certain things are good like getting the name out. Unfortunately, the legality of things, they also hear the bad things 15 or 30. Take this drug and it is great but the side effects could be death, loss of bowel control, or something. So in some cases it makes my job actually harder. Sometimes they come in and ask for a drug and it is absolutely the wrong one for them. There are times it is good and you can use it for your advantage. For example, when

Cymbalta first came out as an antidepressant well, some patients did want to take it because they knew it was an antidepressant. Now recently they got it approved for what is pain control. Now they know it is for pain and they will take it but you can actually get by and use it as an antidepressant. (Dr. B)

Now I love, let me say, I love consumer advertising. I love it because it makes my job easier. Like Abilify. People are ready to accept it. They are ready to take it. On the other hand if it is like that bladder control medicine, that is something you are supposed to report. People sue for taking it, they can make money on it. So there is that part, the part that is negative, but the positive part is really helpful. (Dr. S)

You know, if it's a drug I am familiar with I don't have a particular problem with it. You know some of the pharmaceutical companies have done very well with their consumer advertising. In the old days we didn't have drugs advertised on TV just in journal ads. The bigger problem I see is for drugs I don't know OTC that may be advertised online, supposed to cure this that or the other, you know, herbal remedies or something they think is God's greatest gift to medicine. I say I don't think it will work and try to downplay those but if they are insist, I tell them to go ahead and try it. I suppose a lot of people make a lot of money with these kinds of non-prescription drugs. And I don't get a lot of patients who come in and ask me for advertised prescription drugs. Of course drugs like Viagra, guys use the ad as a way to introduce a problem. Overall, I don't oppose consumer advertising…Yes, as long as it's close to what they are taking and not harmful. I

learned a long time ago if a patient doesn't feel they are getting what they need, they will go to another doctor. Now if it's a reasonable thing we will talk about it, but overall, I am not opposed. (Dr. G)

I would say it affects in you in that it brings disease states to the front normally patients would not talk about. So, for erectile dysfunction people weren't coming in and saying I have erectile dysfunction. With seven minutes to say what's important to them about their heart you don't have a list where you get down to say is everything working all right for you. So direct-to-consumer advertising there made people feel comfortable enough to come to the doctor and talk about it. (Dr. L)

I hate it…I look at the patient and wonder why they want it, if they are short-focused. They are the consumer. Direct to consumer advertising, this should have never happened. The reason is you bring the company between the patient and me. I may not have a problem with the drug, but the patient asks for it, I have to get prior authorization, and then the patient finds out how much it costs and does not want to pay and I have to deal with it. Take testosterone, Androgel, putting these ads all over, testing testosterone has gone up by 1,000%. My prescriptions have gone up by 1,000 %. Whether the patients need it, probably not, many of them are border line and want it.

Now they are talking about how many side effects they have. Nexium, 99% of people does not need Nexium. I am told Prilosec will do the same as Nexium but everyone wants the name Nexium…you increase costs by 1,000 % because of

> direct to consumer advertising. The government should let drug companies and their sales people give information to the doctors and let the doctor decide and not advertise to the consumer. (Dr. A)

Theme 8: Lost Influencer Opportunities: Physicians Need More Dietary Supplement Education (Including N-3 Education) and Lack of Dietary Supplement Curricula in Medical Schools

Physicians who knew the benefits of certain dietary supplements including n-3s, those physicians were more enthusiastic about recommending these products and stated they took a more active role advising their patients to take these products. If physicians were unfamiliar or uncertain about the efficacy, safety, quality, or cost of certain dietary supplements including n-3s, they expressed skepticism and would not recommend such products to their patients. Several physicians explained deficient medical school curricula regarding dietary supplement education.

Physician subjects, in general, desired credible, evidentiary information and education regarding n-3 efficacy, safety, quality assurance of products, and costs. Most physicians expressed more concern about dietary supplement quality assurance than FDA-approved and monitored drug quality. The transcript excerpts below support these findings and accentuate the importance of physician personal experience with dietary supplements and specifically, n-3s:

> It is hard, really hard. Patients come in and tell me they are taking supplements but they have no idea about the quality of these supplements and neither do I…I don’t know what they are taking they could be ordering online or getting these

products anywhere. You just don't know about the quality of these products. I look at supplements and try to determine if a supplement is going to hurt them. You know I've had several people come back to me and say, whether this is a placebo effect or not, "you know I feel better when I take my supplements. I sleep better, my energy is better, I don't know." But I am more confident in a prescription medicine because I feel more confident in what they are getting… There is a lot of evidence and I think more should be taught in medical school, having just gotten out of medical school. I think maybe it might not get recommended or advised. (Dr. F)

[Quality of supplements] Now that…now that…you've got me there. That is something you could definitely put…that I would not be aware of. You know…eh…this one is better than this one because we do this…I don't know that about this particular product…if it's a prescription for a patient I have prescribed then I know that but for this kind of product…if you come in and tell me hey we don't have mercury we go the extra mile then that's darn right I'm going to use your product. That highly influences me. (Dr. H)

It's difficult. I don't know who's doing the studies and how can I judge one manufacturer of omega-3 versus another manufacturer of omega-3? It's a tough thing and usually I am trying to determine if I have heard anything bad about this product and you won't hear me recommend a product unless I know the background. (Dr. R)

Right that's tough, and those [dietary supplements] aren't FDA controlled. We don't learn about those in medical school. And if I don't have a personal interest in it, I don't even know about it so, well some of it I do know something about and some of it comes up in *Prescriber's Letter*. They will provide some information about some of them from time to time. For example, if you have a lot of patients on coral you should know coral can cause deterioration of coronary arteries. And sometimes a patient will come in and say I am on ribo-something or other and I just say, You know I don't know anything about that. I'm not saying you should or shouldn't be on it but I don't know anything about it. So, I don't have to know anything about that. (Dr. O)

If it's an over-the-counter product, I am not sure. I guess the information is available somewhere but if it is, I don't really see it much. I am hoping what they say is in the product is really in there and I am hoping the FDA or somebody is looking over these products to make sure they are OK. That's really about it. For me it's a pretty murky area…for some patients if I do recommend a supplement I tell them to stick with a name brand people know. There's lots of them out there, calcium, vitamin D supplements, but I tend to have them stick with a name brand, a few names that I know of…kinda stick with those. (Dr. N)

Well, a lot of times I don't know what it is and I tell them I don't know and can't give them any advice on it. Yeah, I know there is a big variance on them and I don't have enough information to evaluate them. Quite frankly that is something you don't learn in medical school. I mean that is one supplement I recommend…

so I think the biggest problem you are going to have is getting the information out there…like I said we don't get a lot of this information in school so it depends upon how interested the physician is in the subject and how much time he will spend on it. If you have something the physician can give out to the patient and he knows [the n-3] is a good product, then it is going to go a long ways. And if I know it's a good brand I will recommend the brand and this goes a long way…as long as I know it's affordable. (Dr. B)

Yeah I see patients who say, "I am taking this red yeast rice". I haven't seen that work. (Laughing) But you have fun with that. I have not seen one patient where it worked but they say yeah taking this red yeast rice. I am not going to tell you not to take it but I think you might be wasting your money. I go look I up or Google it. I have an over the counter *PDR* as well. What is it, what is in it and try to find a reputable source. Try to compare something with what the patient is taking. Attempt to tell people not to take supplements very often especially if they are taking something with ephedrine. And if they are borderline high blood pressure and I tell them their problem is this pill. (Dr. T)

When you go out and start buying stuff over the counter, you can't guarantee what patients are going to get. I was talking to a patient the other day and she said I got a bottle of those fish oil pills and they were terrible. I smelled the product and it was fishy nasty. I like pure products with labels that tell what you are getting the DHA and EPA. We know one pill a day meets requirements and if I want to treat someone for high triglycerides I put them on two a day. Well then

the other thing is they go to Sam's and you look at some of their omegas, and they got 6s and 9s combined with 3s. Well that's counterproductive because we are trying to change the ratio between the 3s and the 6s and they're just defeating the purpose…You take the amount of 3's in the puzzle and in fact you're left with very little 3s. In fact it might be detrimental…We want the ratio of n6 to n3 to 3:1 or 4:1, but in our diet it's become 10:1 or 12:1. So you want to get rid of that, and the purity. There was a study done with the athletic trainers, and I think the [*Consumer Reports*] study was done in 2008. And the amount of impurities in the product, it was about a 30% impurity rate. They found traces of arsenic, mercury, PCBs. Our oceans are polluted. (Dr. J)

To tell you the truth those supplements are anything patients can get without prescriptions and without asking the doctors, the majority of them they come to me and they have already been on supplements. And they have been influenced by friends, relatives, TV, magazines, whatever…what I recommend to people if they don't take anything, I recommend a well-balanced diet with a lot of fruits and vegetables, give you the majority of vitamins, nutrients, anti-oxidants that you need. If you want a supplement, a one-a-day multi-vitamin is adequate. If you are a man, I recommend saw palmetto just because of the prostate protection. And men and women, I recommend they take one baby aspirin... unless they have a problem. And women, menopausal, should be on some type of calcium replacement. Like Avista or injectable. For Omega-3, the jury is still out. (Dr. I)

Well I am a big statin user. I have used n-3 along with statin, probably would use n-3 alone. Now a lot of people talk about being on fish oil. I am not sure I always appreciate the kind of fish oil they take, basically if the numbers are where they need to be OK, if not we need to make adjustments. With supplements, the evidence is not quite the same the FDA requires to approve drugs. Not the scrutiny of production, someone could say they have an n-3 but it doesn't have what it says in it. So I caution patients and tell them let's be careful take this stuff and let's see what it does. If it's working, I wouldn't pay an arm and a leg for this stuff. So I guess my approach is cautionary. Except I do see the value of n-3s, a multivitamin, saw palmetto for prostate…when I write a drug I know the dosage, the quality, the side effects. When my patients take an omega-3 I don't know the quality and if they are going to have side effects. A big discrepancy. They probably think they are harmless. (Dr. G)

I had a lady come in the office the other day, showed me a supplement, and the label, because she wanted me to know how wonderful it was and I looked at the label and there were 23 different ingredients. Twenty-three different medications. And I said to her, "You realize there are 23 different medications in this supplement," and she said, "yeah." And I said, "I don't want you to think I am poo-pooing it because I am not, I am telling you there is 23 different homeopathic ingredients here that are medicines, of course they are not natural, they didn't fall off a tree, they went out and filled up the bottle with whatever, so they are not natural processes, that is #1. #2, if you came in here and told me you

had a headache and I gave you 23 prescriptions, would you come back to see me?" "Well, no." That is my feeling, there are some very good, n-3s probably serve a purpose but there are people who abuse supplements because they don't understand what they are doing. That is my personal opinion. (Dr. E)

And with n-3s sometimes I will add to drug regimen. But it's results and that's for all medicines. I don't like a lot of supplements because I don't know what they are putting into them. With drugs, yes but supplements not so much so I allow them to take cinnamon and fish oil and that's it. Way too many brands but if they bring me the bottle I will look at it and I will tell them I don't know what that ingredient is or that one and therefore you should take it…except cinnamon and fish oil. (Dr. D)

I think there is definitely a place for them. I wish they were better studies. Not all of them. Some of them have good studies. Generally speaking, they are not held to the same [quality standards]…And when I am recommending a supplement knowing there are such differences, I am not sure which brand to recommend so that puts a lot back on my shoulders. Or if I recommend the wrong brand a) they are not going to get what they need or b) they are going to get something deleterious. So I feel there is a burden there and I'm not sure it should be my burden. Or at least I am not adequately trained to know. And that's a little bit frustrating. I'll tell you when I have someone who really likes to be on a lot of different supplements and avoid any kind of pharmaceuticals, prescription pharmaceuticals, then I try to direct them to the Internet sites where they can do

the research. You know there are certain sites where they can evaluate the different brands and the different compounds. So I put it back on their shoulders as much as I can. They like to be on a lot of different things. Otherwise I just try to stick to the few things I can trust. (Dr. K)

I hate like hell to tell them to buy fish oil because I have no idea what they are going to end up with…I like the idea of knowing. I like the idea of knowing it's going to be effective, easy for the patient to get, and affordable. So effective, affordable, and compliance. (Dr. S)

It does come up a lot. I tend to get a little more excited about it for healthy people, for prevention. If somebody comes in and they've already had CABG, diabetes, and other problems I am not sure how much this is going to help. But if someone comes in and is healthier, maybe with a family history of heart disease but not eating right, but is overall healthy, this I think is where omega-3s come in and can be pretty beneficial. (Dr. N)

I tried myself to take it, a few months ago. I had such a bad odor in my mouth, fish odor, when I would burp, so I don't know if there is another way to take it to eliminate this kind of side effect, so people more willing to try it…My wife went and got some because I told her we both should try taking n-3 so I don't know what she bought. But man we both had the side effect and then said the hell with it, you know burping fish everyday (laughing)…But when I tell people to put more fish in their diet, they go to McDonalds and get big fried fish. (Dr. I)

When I was writing Lovaza from time to time, and they say to me can't just take fish oil over the counter and my answer to them, remember those Total commercials they use to have, you know you could eat those corn flakes but you would have to eat 14 bowls to get the nutrients in one bowl of Total. So I tell people you have to look at what is equivalent and you would have to take like 16 tablets of your fish oil to get the same fish oil that is in the 4 tablets of Lovaza so you have to decide is it worth it to you to take 14 tablets of fish oil a day. (Dr. T)

You know it's [n-3] been of interest for its anti-oxidant effects for a long time. You know I can't review all the literature and I'll go to lectures and let's say half a day we are going to do cardiology type of stuff. And they present articles which may be inconclusive regarding omega-3. But I have used Lovaza and I've see triglycerides drop 50%. I've seen HDL raise, they'll tell you 20% but I'll tell you maybe 10%. And I haven't see it do much of anything with LDL. (Dr. T)

But you know that's a pervasive one. Almost everybody knows about n-3s. And n-3s have positive effects on inflammatory properties, and cholesterol, I know something about that and I am going to recommend n-3s. But you come in and tell me about something well gingko I know about, but some others I've never heard of, no. Now n-3s, that's easy. (Dr. O)

Applications to Professional Practice

Physician subject comments regarding influencers of their decisions to prescribe or recommend products have broad implications for industry and society. These implications apply to professional practices of health care regulators, physicians, medical school educators, and marketers of drugs and dietary supplements. For regulators, the abundance of conversation and prioritization of cost as an influencer reinforces the effectiveness of insurance company and government policies to drive down health care costs. Also, physician responses supported the need for FDA regulation of DTC advertising and manufacturing quality of drugs and dietary supplement manufacturing quality provide valuable safeguards for society.

N-3 marketers should consider medical school students and residents may benefit from reading the findings of this study regarding dietary supplement education. All 20 physicians interviewed expressed inadequate dietary supplement training in medical school. By providing useful prescribing information, n-3 marketers may facilitate physician-to-patient communication and result in safer and more effective dietary supplement intake among members of American society.

Pharmaceutical marketers may also benefit from other findings in this study. Credible clinical proof, personal experience, and cost are certainly essential influencers of physician decisions to prescribe or recommend products. Other important influencers vary in importance depending upon the physician, but include the influences of peers, pharmaceutical reps, DTC advertising, samples, and dietary supplement education. Regarding clinical trial proof, marketers should present relevant studies published in

respected journals by credible investigators. Studies with optimal design should be double-blind, randomized, and placebo-controlled with a large number of subjects.

Considering the importance of personal experience as an influencer, marketers may increase the emphasis of personal use by physicians or third-party testimonials. During interviews, physicians repeatedly emphasized drug and dietary supplement marketers underestimate the importance of cost. Marketers should disclose clearly costs of medications and supplements to physicians and should make cost disclosure a sales and marketing message priority. Worthy of emphasis, in the physician ladder schema of influencers cost elevated to a primary decision influencer as perhaps the third most important ladder rung after credible clinical data and physician personal experience.

Marketers should remember to serve physicians as customers rather than aggressively attempt to sell them products. Physician subjects provided strong negative responses to deficient pharmaceutical representative skills and lack of tact and consideration of physicians' time. Pharmaceutical marketers may be better off without pharmaceutical representatives than to deploy pharmaceutical representatives without adequate training or with inappropriate service philosophies regarding physician needs. Physicians essentially regarded pharmaceutical representatives with these deficiencies as incompetent. As an extension of pharmaceutical representatives' services, most physicians viewed samples as useful when practical for marketers (i.e., brand name products with no generic substitutes) and samples serve as a potent short-term brand name reminder for physicians, consistent with the findings of Montoya et al. (2010).

Marketers should heed the opinions of subject physicians in this study, who commented consistently regarding the counterproductivity of company managers when accompanying pharmaceutical representatives. Physicians noted the redundancy and inappropriateness of representatives' comments when accompanied by managers. Marketers should ensure field managers understand the needs of their customers and not impose inappropriate or irrelevant sales points during representatives' conversations with physician customers.

N-3 marketers should present credible information and education regarding n-3 efficacy and safety. Because subject physicians expressed more concern about dietary supplement quality and lack of knowledge regarding quality than FDA-approved drugs, n-3 marketers should provide more evidence of quality assurance and purity of n-3 products. Marketers should design easy-to-understand handouts physicians can use to describe and explain the value and differences of quality n-3 products to their patients. Patients' understanding of quality n-3s may be more difficult for lower educated patients less inclined to engage in preventive medicine behaviors (Nelson, Reyna, Fagerlin, Lipkus, & Peters, 2008). A number of physician comments support the positioning and marketing of n-3 products.

For example, Dr. H stated: "For men and women over 40, n-3s would be excellent." Dr. D advised n-3 marketers: "The key may be to let the doctors know and if we know, we will tell our patients." Other physicians also provided important n-3 marketing considerations:

Now as far as something like an omega-3, we already know it is a benefit. Now I am going to be looking at is this product as good as something else. Is it cheaper? Are there going to be side effects from it, like a fish burp…my own personal experience is going to bias me a lot…those are the things I am going to be throwing into my head all at one time. Let me respond back on something. You were talking to me about quality. It is really important for me to know, to be able to say, here is an over the counter product that is high quality. Like Lovaza, I have no doubt this is a supreme product, goes through a lot of testing. They take out the impurities and crap and doesn't have fish oil burp problem the other do and so you know you are getting a uniform product, but if I know there is an over the counter product that is as good or can do as good a job and save the patients $100/month I am happy and my patients are happy…I will be pretty excited about saving patients money and I feel like I am doing the right thing for the right reasons. (Dr. S)

I would love to see a large study that shows the clinical benefit. N-3 arm, no n-3 arm, costs a lot of money to do this, takes it out for a long period of time. And what's your end point, could be heart attacks, strokes, fatal heart attacks, fatal strokes, peripheral arterial disease. (Dr. R)

I have a handout from Mayo in Cleveland and it tells them what to look for in fish oil and I print it out and give it to them. They say the same things as you: the 3:2, you don't want n-6s because you have plenty in the diet already, does not go into specific grams but gives general guidelines this is how much you need…and I am

aware of the patients who have had heart attacks and there are many cardiologists who have all their patients on n-3s and then there are some who say they don't need n-3s because their patients are on statins. And I am not sure who is right and who is wrong depends upon the literature you read. I think the thing is if you have a well-designed marketing piece I can give my patients because if it takes me 30 minutes to explain, forget it. Let me tell you about omega-3s and here is something to read…the 3:2 ratio, the purity, and they can go home and digest it. Now whether it has your branding on it or not. Some give these blatant, retarded pieces and obviously we don't hand them out. They go in the garbage. Well-done handouts help us educate patients and save us time. (Dr. W)

If someone has and LDL of 130 I am probably not going to see if go any lower than 120 but I can get a triglyceride of 250 down to somewhere in the real world, somewhere it should be. And usually we are dealing with a patient who is taking a statin already and I say we got your LDL down to 60 but your triglycerides are still 410 are you eating every carbohydrate you can find? And those are the folks where I say let's try the omega 3's and see what happens. (Dr. T)

You know in medicine we talk about the four A's of success. Ability, Affability, Affordability, and Availability. Those are the four A's of success, there may be fifth one is some schemas. So affability is it packaged well does it look good like it will do the job, ability does it meet the needs of the patient, will it do what it is supposed to do, affordability can the patient pay for it. And then availability and that's where you give them off the shelf at doctor's office, online, and there is

> probably a subset of people who would like one of those the most better than any other, some would work all 3 ways, some only at the store, some hardly ever go to the store vs. online. (Dr. S)
>
> You pretty much touched all bases. Everything we learn today is from our peers, in print or the Internet, and the third one is our reps. So if you want a successful product you have to attack those three areas: you have to have doctors talking among themselves, print and Internet, and pharmaceutical reps. (Dr. I)

Implications for Social Change

From the outcomes of this qualitative phenomenological study, I filled a gap in related literature by providing marketers of drugs and dietary supplements insight regarding how physicians make prescribing decisions. A better understanding can facilitate communication effectiveness between drug and dietary supplement marketers and physicians. Physicians who increase their understanding of drug and dietary supplement usage may improve prescribing efficacy and safety for patients. Physicians' understanding of n-3 preventive cardiovascular disease benefits may result in more frequent physician recommendations of n-3s to their patients, resulting in more n-3 intake in the American population. Nearly all physicians that I interviewed (18 out of 20) opined if our society consumed more purified quality n-3 supplements, our societal risk of cardiovascular disease would decline, especially if members of our society would improve diet and increase exercise.

Recommendations for Further Study

Action defines the top ladder of inference rung, a change in behavior. N-3 marketers may find useful a follow-up study with the same physician subjects to determine if the mere interview and discussion of n-3s resulted in behavioral change (i.e., increased contemplation and prescribing of n-3s). N-3 marketers may devote more study to the optimal design of teaching materials for physicians and for patients. Follow up study with medical schools regarding dietary supplement education is yet another opportunity for further study. Considering the outcomes of this study, a follow-up quantitative study investigators may further substantiate, confirm, and advance the findings of this study. Last, more study could be devoted to understanding the impact of improved dietary supplement training for pharmaceutical representatives as well as field managers.

Reflections

From this experience, I learned more about how physicians determine which drugs and dietary supplements they will prescribe and recommend. I was also exhilarated by the richness of dialogue revealing the inherent goodness and dedication of physicians as caring human beings for their patients. Although I was careful not to interject my personal bias regarding the preventive cardiovascular health benefits of n-3s, the discussion of clinical evidence was strong enough on its own to impassion physicians' convictions to increase their recommendations of n-3s. From an interview-execution standpoint, when physicians freely admitted they did not have adequate n-3 knowledge, I realized asking a few of the detailed n-3 knowledge interview questions was

inappropriate, would have embarrassed physician subjects, and would have negatively affected essential rapport.

Coding and interpretation of data was more complex than I originally conceived. As recommended by professors and cited authors in this document, long periods of reflection aided the crystallization of eight meaningful themes. Additionally, conferring with another coder reinforced the rightness of developed themes and added validity to study findings. As one in the pharmaceutical industry, I may have found physician subject responses more interesting and relevant than to readers outside the industry. Last, my personal skills certainly improved in data collection, data analysis, and reporting of study findings.

Summary and Study Conclusions

The purpose of this qualitative, phenomenological research study was to improve understanding of how physicians reach decisions to prescribe or recommend products and which influencers may be the most important to physicians. The findings revealed three essential influencers including clinical evidence, personal experience, and cost of drug or dietary supplement. Other influencers varied in importance depending upon physician individuality: influence of peers, pharmaceutical representatives, supply of samples, direct-to-consumer advertising, and knowledge of dietary supplements. I developed eight themes related to decision influencers and provided pragmatic recommendations for pharmaceutical marketers. The outcomes from this study may also benefit government regulators, practicing physicians, and medical school educators. Last, the findings of this study, supported by the opinions of 90% of physician respondents, added credence to

omega-3 dietary supplements as an important preventive cardiovascular disease dietary supplement for members of Western society.

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Appendix A: Cochrane Complementary Medicine Field List of Complementary or Alternative (CAM) Therapies

Açaí /Euterpe oleracea

Acupressure

Acupuncture

Acustimulation / acupoint stimulation

African prune / Prunus Africana / Pygeum africanum)

Aiyishu (a Chinese herbal medicine)

Alexander technique

Alpha-linolenic acid (ALA) (an omega-3 fatty acid) supplements

Amino acid supplements

Angelica

Antioxidant supplements

Arachidonic acid (AA or ARA) (an omega-6 fatty acid) supplements

Aromatherapy

Art therapy

Artichoke leaf

Astragalus / Milkvetch (a Chinese herbal medicine)

Auricular acupuncture / ear acupuncture

Ayurveda / Ayurvedic medicine (a type of Indian (East Asian) traditional medicine)

Balneotherapy

Bee stings / bee venom

Beta-sitosterol (a component of saw palmetto)

Biofeedback

Biotin (Vitamin B7) supplements

Botanical supplements

Bovine cartilage

Breathing exercises in mind-body medicine (exclude for physical therapy, eg treatment of cystic fibrosis)

Calcium supplements (many people would not include for prevention of osteoarthritis)

Calendula

Calorie restriction

Carnitine supplements

Cayenne

Chelation therapy (exclude for treatment of medically diagnosed heavy metal poisoning (eg, mercury or lead) and for medically diagnosed excess iron (eg, thalassemia))

Chinese herbal medicine

Chiropractic manipulation

Chitosan supplements

Chondroitin sulfate

Cold laser therapy

Color therapy /chromotherapy

Cranberry

Craniosacral massage

Dance therapy

Danshen (a Chinese herbal medicine)

Dehydroepiandrosterone (DHEA) supplements

Dengzhanhua preparations (a Chinese herbal medicine)

Devil’s claw

Devil’s nettle

Devil’s root / Siberian ginseng / acanthopanax senticosus / ci wu jia)

Dianxianning pill (a Chinese herbal medicine)

Dietary supplements

Dihomogammalinolenic acid (DGLA) (an omega-6 fatty acid) supplements

Dimethylaminoethanol / dimethylethanolamine / Deanol (DMAE)

Docosahexaenoic acid (DHA) (an omega-3 fatty acid) supplements

Echinacea

EDTA (ethylenediaminetetraacetic acid) when used in chelation therapy as described above(see Chelation therapy)

Eicosapentaenoic acid (EPA) (an omega-3 fatty acid) supplements

Electric stimulation therapy

Electroacupuncture

Electromagnetic stimulation therapy

Electromagnetic therapy

Electrotherapy

Elemental diet

Essiac formula

Estrogen (exclude for treatment of natural or surgical menopause) supplements

Evening primrose oil

Eye Movement Desensitization and Reprocessing (EMDR)

Feverfew

Fish oil (omega-3 fatty acids) supplements

Flor·Essence formula

Folic acid / folate (Vitamin B9) supplements (many people would not include for prevention of neural tube defects)

Free and Easy Wanderer (a Chinese herbal medicine)

Gamma-linolenic acid (GLA) (an omega-6 fatty acid) supplements

Garlic

Gerovital H3 (primary ingredient is procaine hydrochloride)

Gerson therapy

Ginger

Ginkgo biloba

Ginseng

Glucosamine supplements

Glutamine supplements

Gluten-free diet

Green tea / Camellia sinensus)

Guiling pa'an wan (a Chinese herbal medicine)

Hemp oil

Herbal medicine

High-fiber diet

Hippotherapy / equine-assisted therapy (exclude when physical therapy only)

Holistic therapy

Homeopathy

Homoharringtonine (HHT) (a plant alkaloid)

Honey

Horse chestnut

Huangqi (a Chinese herbal medicine)

Huperzine A (a Chinese herbal medicine)

Hydrazine sulfate

Hydrotherapy

Hyperbaric oxygen therapy (exclude for treatment of diving disorders or carbon

monoxide poisoning)

Hypnosis / hypnotherapy

Imagery

Iron supplements

Jin Li Da liquor (a Chinese herbal medicine)

Kampo (a type of traditional Japanese medicine)

Kava

Ketogenic diet

Laetrile

Laser acupuncture

Laughter therapy

Lentinan (derived from Shitake)

Light therapy / phototherapy (exclude for treatment of seasonal affective disorder, eczema, psoriasis, neonatal jaundice)

Linoleic acid (an omega-6 fatty acid) supplements

L-isoleucine (an amino acid) supplements

Liuwei dihuang pill (a Chinese herbal medicine)

L-leucine (an amino acid) supplements

Low fat diets

Low protein diets

Low-glycemic index diets

L-threonine (an amino acid) supplements

L-valine (an amino acid) supplements

Magnesium supplements

Magnetic therapy

Marijuana, marihuana / cannabis / cannabinoids / C. sativa / C. indica (exclude for purely psychoactive uses)

Meditation

Mediterranean diet

Melatonin

Milk thistle

Moxibustion

Music therapy

Naturopathy

Niacin / Nicotinamide (Vitamin B3) supplements

Omega-3 fatty acids

Osteopathic manipulation

Ozone therapy

Pantothenic acid (Vitamin B5) supplements

Passiflora

Peppermint

Phytoestrogens

Phytomedicines / Phytotherapy

Plant medicines

Play therapy

Prayer

Prebiotics

Probiotics

Procaine (only when used for aging)

Prolotherapy

Propolis

Protein supplements

Krestin / PSK / PSP (Coriolus Versicolor extracts)

Puerarin (a Chinese herbal medicine)

Pyridoxine / Pyridoxal / Pyridoxamine (Vitamin B6) supplements

Qi Gong

Radiesthesia

Reflexology

Reflexotherapy

Relaxation techniques

Riboflavin (Vitamin B2) supplements

Rolfing®Structural Integration

S-Adenosyl methionine (SAM-e)

Safflower Yellow injection (a Chinese herbal medicine)

Salacia oblonga

Salvia (miltiorrhiza)(injection) (a Chinese herbal medicine)

Sanchi preparations (a Chinese herbal medicine)

Saw palmetto / serenoa repens

Selenium supplements

Shamanistic medicine (Shamanism)

Shark cartilage

Shengmai / shenmai (a Chinese herbal medicine)

Shenqi Fuzheng (a Chinese herbal medicine)

Shensu / shenfu (a Chinese herbal medicine)

Shexiang (injection) (a traditional Chinese medicine]

Shitake

Shuanghuanglian (a Chinese herbal medicine)

Sidda medicine (a type of Indian (East Asian) traditional medicine)

Soy / soybeans

Speleotherapy

Spinal manipulation

Spiritual healing

St. John's wort (Hypericum perforatum L)

Suxiao jiuxin wan (a Chinese herbal medicine)

Tai chi / tai ji

Testosterone

Therapeutic touch

Thiamine (Vitamin B1) supplements

Tianmadingxian capsule (a Chinese herbal medicine)

Traditional African healing

Traditional Arabic medicine

Traditional Chinese medicine

Traditional Indian medicine

Traditional Japanese medicine

Traditional Korean medicine

Traditional Tibetan medicine

Transcranial magnetic stimulation (exclude for treatment of depression)

Transcutaneous electrical stimulation

Tui na

Ultrasound / ultrasonic therapy) (exclude diagnostic ultrasound)

Unani medicine / Yunani medicine (a type of Arabic or Indian (East Asian) traditional medicine)

Valerian

Vegan diet

Vegetarian diet

Visualization techniques

Vitamin A supplements

Vitamin B complex supplements

Vitamin B12 supplements

Vitamin C supplements

Vitamin D supplements

Vitamin E supplements

Vitamin K supplements

Vojta method / Reflexlocomotion

White willow bark

Xiaxingci granule (a Chinese herbal medicine)

Yoga

Zhixian I pill (a Chinese herbal medicine)

Zinc supplements

Zishen Tongli Jianonang (a Chinese herbal medicine)

Adapted from "Development and classification of an operational definition of complementary and alternative medicine for the Cochrane collaboration," by L.S. Wieland, E. Manheimer, & B.M. Berman, 2011, *Alternative Therapies in Health and Medicine, 17*(2), p. 55.

Appendix B: Active Diet Ingredients

Ingredient	Health Benefits	Daily Content (g) in Women, Men
Soybean/soy protein	Cholesterol-lowering, anti-inflammatory	21, 25
Viscous fibers	Cholesterol-lowering, prebiotic, GI-reducing	10-25*
b-glucans		5.8, 6.2
Guar gum		5.6, 6.7
Long chain ω-3 fatty acids	Triglyceride-lowering, anti-inflammatory	2.4, 3.0
Almonds	Cholesterol-lowering	28, 28
Plant stanols	Cholesterol-lowering	2.0, 2.7
Cinnamon	Antioxidant	3.0, 3.0
Blueberries	Antioxidant, prebiotic	74.5, 94.5
Vinegar	GI -reducing	22.5, 22.5
Probiotic	Cholesterol-lowering, anti-inflammatory	0.1, 0.1
Whey protein	GI-reducing	4.3, 4.3

Note. Adapted from "A diet based on multiple functional concepts improves cardiometabolic risk parameters in healthy subjects," by J. Tovar, et al., 2012, *Nutrition & Metabolism, 9*(1), p. 6.

Appendix C: Informed Consent Form

Dear Potential Participant,

You are invited to take part in a research study entitled Physician Ladders of Inference Regarding Omega-3 Dietary Supplements. The researcher will seek to gain an understanding of how physicians make decisions to prescribe or recommend dietary supplements, especially omega-3 (n-3) dietary supplements. This form is part of a process called "informed consent" to help you understand the intent of the study before deciding to take part. This study is being conducted by Warren P. Lesser, a doctoral student at Walden University. You may already know Mr. Lesser is associated with a pharmaceutical company, but this study is separate and conducted in a student role. Protective measures have been implemented to prevent conflict of interest bias. Absolutely no persuasive or coercive measures will be used to influence you to prescribe or recommend any products.

Background Information:

The purpose of this study regards n-3 marketing strategy to determine decision criteria and the ladder of inference physicians use to recommend n-3 supplements. The business problem is the difficulty in communicating the complex mechanisms of n-3s and their profound health benefits to physicians and subsequently from physicians to their patients. Positive potential study outcomes regard preventive cardiovascular health opportunities: a) N-3 marketers may understand how to improve n-3 marketing and communication with physicians, b) increased physician education and n-3 utilization may

lower healthcare costs, and c) patients and the general population may improve cardiovascular health and quality of life.

Number of Subjects/Length and Description of Participation

This study will include 20 physician subjects from a geographical region including Indiana, Kentucky, and Tennessee. Interview time lengths will be limited to 1 hour. The interview will be audiotaped to maintain the accuracy of all data collected. Additionally, each subject will be asked to provide feedback via e-mail to confirm interview data collected and provide additional feedback if desired. Themes may be disclosed among group members but group member names will be kept strictly confidential and not disclosed to other group members). You may be asked to respond to no more than two follow-up e-mails. E-mail feedback will take no more than 10 minutes per e-mail.

Inclusion Criteria

Physician subjects will be purposefully selected based upon interest in the study subject, an open perspective regarding diverse opinions, and access. Geographical scope and a willingness to set aside sufficient time without interruptions in a private setting define acceptable participant access criteria.

Procedures:

If you agree to voluntarily participate in this study, you will be asked to:

Participate in a one-on-one interview with the researcher regarding decision processes used to recommend dietary supplements particularly omega-3s and respond to

no more than two follow-up emails to verify/clarify collected interview data and identified themes.

Here are sample questions:

2a, 2b, 2c. (a) What credible clinical evidence have you seen regarding fish oil dietary supplements? (b) What made the evidence credible or incredulous? (c) What kind of evidence would you consider the most convincing?

3. What are the risks of taking fish oil dietary supplements? What are the risks regarding specific patient groups or disease states?

4a, 4b. (a) What are the important differences between quality fish oil dietary supplements and low quality fish oil dietary supplements? (b) What are right daily amounts of DHA and EPA?

Voluntary Nature of the Study:

This study is voluntary. If you decide to join the study now, you can still change your mind during or after the study. You may stop at any time. You may withdraw at any time during the study. If you choose not to participate or withdraw, you will not receive the $50 stipend and the relationship between the study subject and researcher will not be deleteriously affected.

Risks and Benefits of Being in the Study:

Being in this type of study involves some risk of the minor discomforts that can be encountered in daily life, such as stress or becoming upset. Being in this study would not pose risk to your safety or wellbeing. Any risk of physical injury or harm during the study interview is virtually nonexistent. Other risks of participation include loss of time

and disclosure of personal prescribing preferences and decision processes to the interviewer, transcriber, and one other coder. The interviewer, transcriber, and coder must execute confidentiality agreements before data access. Positive potential study benefits include: a) Gained knowledge among n-3 marketers to better communicate with physicians, b) increased physician education and n-3 utilization, which may improve patient health, patient quality of life, and lower U.S. healthcare costs.

Payment:

Participation in this study is voluntary but an appreciation stipend of $50 will be paid at the conclusion of data collection. If you withdraw from this study you will not be paid the $50 stipend.

Privacy:

Any information you provide will be kept confidential. The researcher will not use your personal information for any purposes outside of this research project. Also, the researcher will not include your name or anything else that could identify you in the study reports. The privacy of all participants will be protected with all sensitive data coded in place of source identification. All study protocol, collected data, and consent forms will be stored in a locked container for 5 years from completion of the study.

Contacts and Questions:

You may ask any questions you have now. Or if you have questions later, you may contact the researcher, Warren P. Lesser, via telephone or email: or [redacted]. If you want to talk privately about your rights as a participant, you can call Dr. Leilani Endicott. She is the Walden University representative who can

discuss this with you. Her phone number is [redacted], extension [redacted]. Walden University's approval number for this study is [TBD]. The researcher will give you a copy of this form to keep.

Statement of Consent:

I have read the above information and I feel I understand the study well enough to make a decision about my involvement. By signing below, "I consent," I understand I am agreeing to the terms described above.

Printed Name of Participant

Date of consent

Participant's Signature

Researcher's Signature

Curriculum Vitae

Warren P. Lesser

Experience

Campbell Soup Company, Scarsdale, NY (Sales, 1976-1978)

Boots Pharmaceuticals, Shreveport, LA (Sales and Manager of Sales Training,1978-1987)

MAS Home Health, Shreveport, LA (VP Marketing, 1987-1988)

SpectraCare, Inc. (Home health and I.V. infusion pharmacies, owner/founder, 1988, harvested in 1996)

SpectraBrace, Ltd. (Orthopedic services, owner/founder, 1996, harvested in 2005)

Paradigm HealthCare Solutions, Inc., Louisville, KY (ICD-9 coding, owner/founder, 1996, harvested in 2004)

MAGNA Pharmaceuticals, Inc. (President/CEO, primary owner, 2000 – present)

Z-Xpress Car Wash, LLC, Louisville, KY (conveyor and conveyor/detailing locations, owner/founder, 2005 - present)

Hogg's Upstairs Taverne Gatlinburg, TN (owner/founder, 2008 - present)

Hogg's Pub & Grub, Gatlinburg, TN (owner/founder, 2012 – present)

LandVest, LLC, renamed LV Capital, LLC, Louisville, KY (1/3 partner in patio home development company, 1996-2008)

Education

Taylor University, Upland, IN, Bachelor of Arts, 1976

MBA course work, Indiana University at Fort Wayne, 1979-1980

Centenary College of Louisiana, Shreveport, LA, Master of Business Administration, 1987

DBA course work, Walden University, 2010-2014