

Regulation of Supplements and the Consumer Decision Making Process

Robert E. Wright
University of Illinois at Springfield

Consumers make a variety of purchase decisions. They may rely on information from marketers to make those decisions. When the legal environment is such that marketers are able to make broad claims about product efficacy without being subject to a high level of government scrutiny, the quality of the consumer decision making process may suffer. This paper explores how regulation of supplements impacts the consumer purchase decision making process.

INTRODUCTION

Consumer purchase decision making is a widely studied area of consumer research. Frequently, the consumer may face a decision process where they are unable to accurately assess the performance of a product prior to purchase. In some instances, the consumer may not even be able to accurately assess a product after using the product. This may be especially true of products marketed to have positive health benefits to consumers. In such a case, why are consumers unable to accurately assess the performance of a product, and how are marketers able to use this lack of accurate assessment in their marketing throughout the Consumer Purchase Decision Process? This paper discusses the difficulty consumers may face in determining the efficacy of certain health related products such as supplements, and the implication for marketers.

Review of Literature

Most decision making is under conditions where the consumer has some uncertainty. Such decision making may present challenges for both the consumer and the marketer. For example, Platt & Huettel (2008) examined brain scans of subjects making different types of decisions under uncertainty. They noted that different areas of the brain were activated, depending on the type of decision being made. Tversky and Kahneman (1974) discussed the mechanics of how people make decisions under uncertainty. Uncertainty may make a decision very complex for consumers, driving them to attempt to simplify the decision making. Other researchers such as Johnson and Payne (1985) also noted that people prefer to limit their cognitive efforts in decision making, and use some simplifying strategy to limit that effort.

The purchase process for a supplement would involve a great deal of uncertainty on the part of the consumer. The consumer would not typically be in the position of undertaking an extensive research study to determine a particular supplement's efficacy. Therefore, the consumer would be likely be heavily dependent on the marketer and/or anecdotal or other data in making a purchase decision for a supplement.

Knowledge of the process consumers go through in the decision making process may provide significant aid in allowing marketers to more effectively market their products. This may be particularly the case with

the marketing of supplements for non-specific purposes. Laws regulating supplements allow marketers to make general claims, but disallow claiming any specific health related outcomes (FDA website, Accessed 3-15-18). Given the legally mandated lack of specificity in health claims for supplements, a wide range of positive outcomes may be perceived by consumers as direct result of taking a given supplement.

Kerin and Hartley (2016) describe the Consumer Purchase Decision Process as a five stage process. The process starts with Problem Recognition, then proceeds to Information Search, Alternative Evaluation, Purchase Decision, and Post Purchase Behavior. Throughout each of these stages, marketers can adjust their marketing efforts to better target their segment of interest. This process is actually facilitated by laws regulating supplements meant to impact health.

Thompson (2005, p. 26) discusses the difficulty, in general, of determining whether a treatment is effective. He notes that:

Treatment benefit = Therapeutic gain + Natural History of Illness + placebo effect. He further defines the Therapeutic gain as the effect on a Patient's symptoms or abnormality by the treatment itself, the Natural History as the state of a patient's symptoms or abnormality that would exist at the end of the trial if no treatment were given, and the Placebo effect as a beneficial effect on the patient's symptoms or abnormality that is not a function of the properties of the treatment, or the natural history of the symptom or abnormality.

In order to conclude the positive, statistically significant effect of a supplement on a person's health, it would be necessary to develop an experimental design using an experimental and control group, and having a double blind, where neither the subjects nor the experimenter knew which group was the experimental group, and which was the control group.

Clearly, this would not be the case with consumers taking supplements. Consumers would simply start taking a supplement, and any improvement in health would typically be attributed to taking the supplement. Consumers would have no way of knowing whether the positive result was due to the therapeutic gain, the natural history of the illness, or the placebo effect. As an example, if a consumer got a cold, they might start taking a supplement to help "cure" the cold. After a week or so, the consumer might feel much better. Did the supplement product the positive impact on the consumer's health? Would the consumer have seen the same improvement due to natural processes in the body as it responded to the cold? Did the consumer feel better because they thought the supplement would help them feel better? Many, if not most, consumers would attribute the positive results to taking the supplement.

In fact, reviews of multiple academic studies have shown supplements to have minimal or no impact on chronic diseases (Fortmann, Burda, Senger, Lin & Whitlock , 2013; Guallar, Stranges, Mulrow, Appel, & Miller III, 2013).

Legal Issues

According to the FDA website, "Unlike drugs, *supplements are not intended to treat, diagnose, prevent, or cure diseases.* That means supplements should not make claims, such as "reduces pain" or "treats heart disease." Claims like these can only legitimately be made for drugs, not dietary supplements." The basic information about supplement claims (from the FDA website) appears below:

Structure/Function Claims and Related Dietary Supplement Claims

"Structure/function claims have historically appeared on the labels of conventional foods and dietary supplements as well as drugs. The Dietary Supplement Health and Education Act of 1994 (DSHEA) established some special regulatory requirements and procedures for using structure/function claims and two related types of dietary supplement labeling claims, claims of general well-being and claims related to a nutrient deficiency disease. Structure/function claims may describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body, for example, "calcium builds strong bones." In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity." General well-being claims describe general well-being from consumption of a nutrient or dietary ingredient. Nutrient deficiency disease claims describe a benefit related to a nutrient

deficiency disease (like vitamin C and scurvy), but such claims are allowed only if they also say how widespread the disease is in the United States. These three types of claims are not pre-approved by FDA, but the manufacturer must have substantiation that the claim is truthful and not misleading and must submit a notification with the text of the claim to FDA no later than 30 days after marketing the dietary supplement with the claim. If a dietary supplement label includes such a claim, it must state in a "disclaimer" that FDA has not evaluated the claim. The disclaimer must also state that the dietary supplement product is not intended to "diagnose, treat, cure or prevent any disease," because only a drug can legally make such a claim. Structure/function claims may not explicitly or implicitly link the claimed effect of the nutrient or dietary ingredient to a disease or state of health leading to a disease." (FDA website, Accessed 3-15-18)

Basically, the law enables supplement manufacturers to make general claims such as "maximum strength formula for healthy joints," as long as they do not make specific claims to *treat, cure or prevent any disease*.

The legal regulations related to supplements thus provide an opportunity for manufacturers to "suggest" potential product benefits without explicitly claiming such product outcomes.

Marketing throughout the Consumer Decision Making Process

The Consumer Purchase Decision Process starts with the Problem Recognition stage. In this stage, marketers need to help consumers realize they have an unmet need or want. Due to the huge number of potential health related issues consumers face on a regular basis, this provides a huge potential target segment for marketers. Marketers can focus on common health related issues, and the need for relief from such problems, and thus position their products as potentially providing relief from health issues.

The next stage is the Information Search stage. Consumers search internally first, searching their memory for information about their need or want. Marketers of health related supplements can use a variety of frequently occurring advertisements to get the information about their product into consumers' minds. Due to the laws regulating supplements, marketers can make general claims throughout the course of their ads, implying that their products will help alleviate the problem, as long as a disclaimer is used somewhere in the ad. Consumers are likely to remember claims made in ads for supplements, but may overlook the disclaimers at the end of such ads.

For the external part of information search, consumer look to personal sources, public sources, and marketers for information.

Personal sources include friends and relatives. Many friends and relatives may have tried supplements. Due to the nature of most minor health afflictions, which are temporary in nature, these friends and acquaintances may perceive that the correlation between taking a supplement, and the eventual end of the health affliction implies that the supplement was responsible for "curing" them of the affliction. Most will not take into account the natural history for improvement in health, or the placebo effect as the reason for the improvement in health. Given the strong influence of friends and relatives over consumer purchase behavior, this endorsement by friends and relatives may be extremely persuasive.

Public sources include publicly available information. There is a limited amount of publicly available information available on supplements and impact on health, as most of the pertinent research is done by supplement companies themselves. In addition, consumers do not appear to be affected by published research indicating lack of efficacy of supplements (Tilburt, Emanuel, & Miller, 2008). This could be the result of the way consumers search for information. Consumers would not typically search published academic journals for information concerning the efficacy of supplements. Consumers would more likely use information from the general media sources such as television, radio, newspaper, or internet sources. News media outlets would be unlikely to focus much time and effort on reporting a study which found no impact of a supplement on consumer health.

Marketers provide the final potential source of information. Given the nature of supplement regulations, marketers are free to make general claims, as long as they do not make any specific health related claim, and they include a disclaimer. Therefore, marketers can make a wide variety of general assertions about their

products. This can give consumers a misleading idea that the efficacy of the supplement has been tested and established. Given the lack of widely available public information to refute such claims by marketers, consumers would be likely to remember such claims, and would tend to believe such claims.

The next step is alternative evaluation. Consumers seek to evaluate potential alternatives uncovered during the information search stage. Supplement manufacturers seek to emphasize criteria which they feel that they excel at. Given the wording of the laws regulating supplements, supplement manufacturers can again emphasize the “general” relief their products may provide. They can also focus on attributes such as “all natural,” and they can offer products at a lower price than traditional drugs, which have high costs due to the extensive testing necessary to demonstrate efficacy and safety. There is some evidence that supplements are used to replace traditional, more expensive health care options (Cathcart & Maag, 2009.) The purchase stage would be similar to other products.

At the post purchase stage, consumers evaluate how satisfied they are with the purchase. Given the difficulty of determining the treatment effect, as discussed earlier, consumers are likely to be satisfied with the outcome of using the supplement. Consumers may get better due to the natural progression of the malady. They also may improve due to the Placebo effect. However, any improvement will be attributed to the supplement.

CONCLUSION

Due to the legal environment under which supplement manufacturers operate, and the fact that many consumers fail to take into account the natural history effect and the placebo effect when evaluating the efficacy of supplements, the manufacturers and marketers of such supplements are able to very effectively market such product throughout the consumer purchase decision process.

Implications

The legal environment can have an immense impact on the marketing of products. This may be particularly true of products where it is difficult for consumers to properly evaluate efficacy. Given the heavy regulatory burdens placed on marketers of products classified as drugs, consumers may believe that supplements are similarly regulated, and thus be more likely to feel that the claims made by marketers concerning supplements have been evaluated by the government.

Suggestions for Future Research

Future research should attempt to discover how often does the legal environment interact with the limited ability of consumers to properly evaluate the efficacy of various product classes. Specific attention should be paid to the extent to which consumers believe that supplements are regulated in a similar fashion to drugs. Research should also be conducted to determine if consumers read and understand the mandated disclaimers on supplement packages, and in supplement advertising.

REFERENCES

- Cathcart, R., & Maag, C. (2009). As the economy is down, vitamin sales are up. *New York Times*, April 4, n 2009, p. A22.
- Food and Drug Administration (2018). Dietary supplement products & ingredients, <https://www.fda.gov/Food/DietarySupplements/ProductsIngredients/default.htm>, accessed 3-15-2018.
- Food and Drug Administration (2018). Label claims for conventional foods and dietary supplements, <https://www.fda.gov/food/labelingnutrition/ucm111447.htm>, accessed 3-15-2018
- Fortman, S.P., Burda, B.U., Senger, C.A., Lin, J.S., & Whitlock, E.P. (2013). Vitamin and mineral supplements in the primary prevention of cardiovascular disease and cancer: An updated systematic evidence review for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*, 159 (12), pp. 824-834.
- Guallar, E., Stranges, S., Mulrow, C., Appel, L., Miller III, E.R., (2013). Enough is enough: Stop wasting money on vitamin and mineral supplements. *Annals of Internal Medicine*, 159 (12), pp. 850-857.
- Johnson, E.J. & Payne, J. W. (1985). Effort and accuracy in choice. *Management Science*, 31 (4), pp. 395-414.
- Kerin, R. A. & Hartley, S. W. (2016). *Marketing: the core*. McGraw-Hill Education, 2 Penn Plaza, New York, NY 10121.
- Platt, M. L. & Huettel, S.A., (2008). Risky business: the neuroeconomics of decision making uncertainty. *Nature Neuroscience*, 11 (4), pp. 398-403
- Thompson, W. G.,. (2005). *The placebo effect and health: Combining science & compassionate care*. Prometheus Books, 59 John Glenn Drive, Amherst, New York 14228-2197.
- Tilburt, J.C., Emanuel, E.J., & Miller, F. G. (2008). Does evidence make a difference in consumer behavior? Sales of supplements before and after publication of negative research results. *Journal of General Internal Medicine*, 23 (9), pp. 1495-1498.
- Tversky, A. & Kahneman, D. (1974). Judgment under uncertainty: Heuristics and biases, *Science*, 185, pp 1124-1131.