health claims put out by FOSHU are not completely without grounds, they are not produced with the lifestyles of consumers in mind [12]. This puts the value of FOSHU products into question. Is the increased price value supported by the results experienced by the general public? Although Suzuki's study was not published in a journal, the results were compelling, and he was not the only one who questioned the efficacy of FOSHU.

One big factor in analyzing FOSHU effectiveness is consumer compliance with instructions for consumption. However, the average consumer does not always know to follow the label instructions, or why they are so important. While there is a shortage of information on steps taken to educate the public on the proper use of FOSHU and the dangers of improper intake of the functional food products, there are a few studies detailing the level of ignorance of the public, as well as the dangers that the average consumer faces. Dr. Chiba from the National Institute of Health and Nutrition in Japan specializes in the department of Food Function and Labeling and has published a few papers on the topic of FOSHU. He notes that FOSHU can be a valuable tool when "consumers correct their lifestyle appropriately" [13]. However, it seems that many consumers of FOSHU products do not follow this guideline. A large percentage of consumers took FOSHU as a way to maintain their health and a smaller percentage used them for the prevention or treatment of disease. While FOSHU packages are labeled appropriately, only about 60% of consumers followed the directions, another 20% did not follow directions at all, and the remainder were unaware of the directions on the packaging, indicating that in that situation, "only 23.4% of users gained beneficial effects from FOSHU" [13]. Further analysis of the data showed the extent of FOSHU's effectiveness. Only 30.2% of users who modified their diet, along with 17.0% of those who modified their exercise routines and 10.1% of those who made no modifications on their lifestyle experienced beneficial effects from FOSHU. Moreover, the study revealed improper usage of FOSHU among consumers on medications, which has the potential to be harmful [13]. As a follow up study, the usage of FOSHU along medication to treat diseases and illnesses was examined. It was found that the percentage of those who use FOSHU to treat illnesses rose with age and the practice was significantly higher in patients actively seeking medical attention compared to those who are not [14]. Meanwhile, only 14.6% of these patients disclosed this to their physicians. FOSHU is often found in the form of common food, so the chance of interaction with medicine is small, and yet due to this potential, usage of FOSHU products should be disclosed to physicians [14]. Chiba's findings show that while there has been a great effort to gain public trust in FOSHU, proper use and warnings have not been stressed nearly enough. This adds another aspect to the study concerning the opinions of pharmacists regarding their patients' use of health products; not only do the pharmacists and possibly other health professionals have a poor understanding of these products, but patients also fail to follow specific instructions set by the manufacturers for optimal results. This leads to miscommunication that lowers the potential of FOSHU significantly.

The lack of knowledge of the public regarding the use of FOSHU has led to marginal results in consumers and a decrease in confidence in the products. A study concerning the usage of dietary oil products which are approved as a FOSHU product found that there was a lack of belief in the efficacy of FOSHU among female university students studying health sciences [14]. Out of 1223 participants, 47%

had experience using the products and 69% used the FOSHU products because their families were also using them. The target individuals for these products were those with a body mass index of 23 or greater and while 49% of participants knew the requirements for product usage, only 13% were actually target individuals and less than 1% of those participants believed that the FOSHU products they were using are effective [15]. One major reason for the lack of belief in FOSHU could be attributed to non-target individuals using products specifically made for certain conditions, and especially with products such as oil, consistent quantities are difficult to consume. Therefore, the effects of the FOSHU product might be hard to notice [15]. Table 5 summarizes the criticisms of the FOSHU system for consumers.

Table 5: Shortcomings of the FOSHU approval process for consumers.

Criticisms of FOSHU Process for Consumers
• High Prices ○ Due to lengthy approval process, products end up costing too much for lower-income families. This excludes large portions of population from benefiting from health effects.
• Lack of After Market Research ○ Follow up research allows for refinements after products are released to increase efficacy and test in uncontrolled environments. ▪ No research results in products that do not mimic the uncontrolled setting of real-life consumption in the public. ▪ Consumers cannot most effectively benefit from FOSHU products.
• Lack of Education to the Public and Healthcare Professionals ○ Most consumers do not properly follow label instructions or know why they are important. ○ Many consumers do not use product for its intended use or in conjunction with appropriate lifestyle (i.e., diet and exercise). ○ Only 14.6% of consumers know to disclose the use of these products to their physicians. ○ Some health care professionals (pharmacists) lack knowledge and comfort with these products (i.e., adverse reactions with medications).

The Functional Food Center has placed a lot of effort into educating the public about functional foods, their uses, and their benefits. Along with publishing peer-reviewed journals, organizing international conferences, and creating educational materials such as textbooks used in universities, the Functional Food Center also created the Academic Society for Functional Foods and Bioactive Compounds (ASFFBC). The ASFFBC was established in order to unify the scientific and medical communityaround functional foods [2]. This is a critical step in the improvement of functional foods worldwide.

CONCLUSIONS

In the past, the Functional Food Center has investigated how the FOSHU system operates in Japan, and how the Functional Food Center's vision of functional foods should be regulated in the US. However, this article dug deeper in discovering the efficacy of the FOSHU system in practice. Specifically, in this review, the general market for FOSHU, the impacts of the FOSHU seal on consumer trust, as well

as the shortcomings of the system have been discussed. The FOSHU regulation system on health claims has helped manage false or exaggerated health claims that were prevalent in the time before its implementation. Under FOSHU and its derivatives, the market for functional foods has been able to grow in Japan and trickle down to the rest of the world. Still, although FOSHU has been around for thirty years, its market is still rather limited in Japan. A large portion of its consumers are in the older age range, and as discussed before, socioeconomic factors do play a role in the consumption of those food products. This shows that there is still a significant portion of the population that does not have access to FOSHU products, either due to lack of knowledge or lacking abilities to purchase the products. Furthermore, from the limited aftermarket research found on FOSHU food products, there is a lack of proper consumption by consumers, as well as missing research for the efficacy and safety of these products in an uncontrolled setting. The consequences are reduced benefits from possibly well functional products. A pattern that has emerged in this review is the marketing of FOSHU towards a population that is too general. Although FOSHU packaging does provide information as to who target individuals are, the general public is not aware of the importance of the information. Providing more specific marketing along with better education regarding the limitations of the products can increase the overall function of FOSHU products.

Taking some of the possible routes of improvement suggested by the Functional Food Center, such as increase in public education in functional food and more specific instructions and duration of consumption might be realistic ways to improve overall results. This, along with the introduction of epidemiological studies post-market in order to assess the effectiveness of a functional food, can aid in the development of functional foods as a science around the world. In the United States specifically, the introduction of a functional food sector can provide a means to gain public trust in the health food they purchase. In order to avoid mistakes seen in the Japanese systems, encouraging not only after-market research, but research that challenges the system's efficacy can expose issues in an orderly manner and bring constructive change to food regulations.

This paper sought to review the effectiveness of the FOSHU system. However, there were limitations to the scope of information available. After-market research seems to be scarce in regard to FOSHU, and some sources found were in Japanese, making it difficult to use the information they contained. Instead, their abstracts were used to draw data and conclusions.

Abbreviations: FOSHU: Foods for Specified Health Uses, EU: European Union, MHLW: Ministry of Health Labor and Welfare, GMOs: Genetically modified organisms, FDA: Food and Drug Administration, FNFC: Foods with Nutrient Function Claims, FHC: Food with Health Claims, FFC: Food with Functions Claims, MWTP: marginal willingness to pay, CAA: Consumer Affairs Agency, SRs: systematic reviews, ASFFBC: Academic Society for Functional Foods and Bioactive Compounds.

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