

Dietary Supplements and Medical Foods

A growing body of evidence suggests that eating a healthy diet and maintaining balanced nutrition may contribute to decreasing the risk for cognitive decline and dementia. However, no single food, beverage, ingredient, vitamin or supplement has been proven to prevent, treat or cure Alzheimer's disease, or benefit cognitive function or brain health.

In the United States, a product can only be considered a medical food if it is designed to treat a condition that has a "distinctive nutritional requirement." According to the Food and Drug Administration (FDA), Alzheimer's dementia, as currently understood, does not have a distinctive nutritional requirement, and therefore, in the United States, no product can legitimately be described as a medical food for Alzheimer's.

Other countries have different definitions of the term "medical foods," and products are available for sale as medical foods for Alzheimer's disease in several countries. While research on some products may have been conducted in preliminary clinical studies, none of these products have been proven to address "nutritional requirements" of people with Alzheimer's disease or to safely or effectively treat the disease.

The Alzheimer's Association is aware of a variety of products, including foods and supplements, that falsely claim to be beneficial for people living with Alzheimer's or to support memory or brain health. The FDA continues to alert consumers that they should watch out for false promises about so-called Alzheimer's cures. These claims are misleading for several reasons:

• In contrast to "conventional" food and drug products, <u>dietary supplements</u> are not subject to the FDA's rigorous review and regulation process. Because of the <u>lack of this review before the products are marketed</u>, the Alzheimer's Association, the medical community and consumers cannot be assured that data (if any) supporting the products' safety and effectiveness have undergone scientific scrutiny. Without large-scale, controlled clinical trials, no declarations can be made about how well supplements deliver the nutrient ingredients, much less achieve any claimed benefits. Conclusions or claims related to safety and effectiveness remain speculative until such trials are carried out.

In addition, the <u>FDA does not currently oversee</u> the manufacturing of dietary supplements. Each manufacturer and distributor of dietary supplements must meet all safety and labeling requirements of the Dietary Supplement Health and Education Act of 1994 (DSHEA) and the FDA. Most in the industry act responsibly, but some adulterated or misbranded products have made it to market. Therefore, people with Alzheimer's and their families have no absolute guarantee that supplements contain the ingredients listed on the label in the specified amounts.

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• Finally, the lack of rigorous research for these products means little (or nothing) is known about their effects when taken in combination with approved drugs. For example, we often do not know whether the products will interact with, and possibly decrease, the effectiveness of approved drugs taken for Alzheimer's and related dementias. In fact, many dietary supplements are known to interact with legitimate, much-needed medications, making this a very real concern.

The Alzheimer's Association welcomes <u>action by the FDA</u> in sending warning letters to companies that are illegally selling dietary supplements that claim to prevent, treat or cure Alzheimer's disease or to benefit cognitive abilities or brain health. To best serve individuals with Alzheimer's and their families, the Alzheimer's Association strongly encourages makers of products that claim to be beneficial for those with Alzheimer's or other dementia to conduct definitive clinical trials.

The Alzheimer's Association will continue to monitor dietary supplements and medical foods that make claims about treating Alzheimer's and other dementia. The Association will also continue to monitor advances in Alzheimer's science, including those related to nutrition, that may warrant revisiting its positions about these products.

Individuals with Alzheimer's disease and other dementia, and their caregivers, are strongly encouraged to have conversations with their physicians about all medications, any dietary concerns and dietary supplements, including multivitamins and beverages they are taking or interested in starting. This will enable their doctors to provide advice regarding nutrition, to evaluate the potential of these products to cause any unintended side effects, and to consider how these products may interact with their medications.

- Alzheimer's Association Medical and Scientific Advisory Group, reviewed January 2023