

Can probiotics enhance immune function, prevent disease?

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Editor's note: *This is the first of a three-part series on prebiotics, probiotics and dietary supplements.*

Dietary supplements are taken by mouth and contain one or more of the following: probiotics, prebiotics, vitamins, minerals, herbs or other botanicals (excluding tobacco), amino acids, enzymes or tissue extracts.

Probiotics are live microorganisms. Frequently used probiotics in the United States include species from the genera *Saccharomyces*, *Bifidobacterium* and *Lactobacillus*.

Prebiotics are substances such as fiber that are not digestible in the human intestinal tract but can act as substrate for the intestinal microflora, including bacteria and fungi.

The basic premise of both probiotic and prebiotic use is that the microbial population in the intestine can be manipulated to benefit the host. Frequently cited reasons for use of probiotics or prebiotics include disease prevention (wellness), enhanced immune function, increased energy and improved memory.

Proposed mechanisms of actions of probiotics are variously described as modulation or enhancement of the immune response, interactions with other gut flora, production of certain organic acids such as lactic acid, competitive replacement or modification of existing gut flora, improvement of the mucosal barrier and secretion of beneficial small molecules such as bacteriocins (compounds that have antimicrobial activity) or enzymes. However, it is important to note that results from rigorous studies are not available to substantiate these claims.

Which of the following are true?

- a) Echinacea has been shown to cure the common cold.
- b) *Ginkgo biloba* is useful in patients with dementia.
- c) Some herbs can cause serious side effects when mixed with prescription and over-the-counter medications, such as aspirin, anticoagulants or medications for hypertension.
- d) One of the first investigators to evaluate probiotics was Élie Metchnikoff.

Answer: c and d are true

The Food and Drug Administration (FDA) regulates dietary supplements, but the laws for manufacturing dietary supplements such as probiotics and prebiotics are less strict than those for prescription drugs. Unlike pharmaceutical companies that make products such as prescription medications and vaccines, makers of probiotics are not required to demonstrate efficacy.

Manufacturers are not required to obtain FDA approval before selling dietary supplements. Companies can make claims about how the product affects the structure or function of the body, if a disclaimer is included that the FDA has not evaluated the claim. In contrast to a drug, dietary supplement labels cannot claim to diagnose, treat, cure, mitigate or prevent disease.

Manufacturers are required to follow good manufacturing practices to ensure that supplements are processed consistently and meet specific quality standards. If a product is found to be unsafe, the FDA may require the product to be removed from the market.

In the United States, probiotics generally are marketed to healthy people as a dietary supplement and not as a drug. FDA regulations define a drug as a substance (other than food) recognized by an official pharmacopoeia or formulary that is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease and is intended to affect the structure or any function of the body (<http://bit.ly/33Q2g26>). If a probiotic is intended to be marketed as a drug, it first must satisfy regulatory requirements, including submission of an Investigational New Drug application that demonstrates safety and effectiveness for the intended use.

Some dietary supplements have been found to contain potentially harmful products that are not listed on the label, including anticoagulants (warfarin) or anticonvulsant medication (phenytoin). From 2004 through 2015, an estimated 23,000 U.S. emergency department visits each year were attributable to adverse events related to dietary supplements and resulted in 2,000 hospitalizations (Geller AI, et al. *N Engl J Med*. 2015;373:1531-1540).

Élie Metchnikoff, a Russian zoologist who is known as the father of immunology for the Nobel Prize winning discovery of macrophages, first considered intestinal microbes as causative agents of aging. He observed that Bulgarian peasants who consumed large quantities of sour milk containing *Lactobacillus bulgaricus* lived longer than others. He postulated that lactic acid-producing bacteria in sour milk had a beneficial effect by inhibiting the growth of potentially harmful intestinal bacteria.

The 2012 National Health Interview Survey showed that about 4 million (1.6%) U.S. adults and 300,000 children ages 4 to 17 years had used probiotics or prebiotics in the previous 30 days. Among adults, probiotics or prebiotics were the third most commonly used dietary supplement behind vitamins and minerals.

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