

Women's Health

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How Safe Are the Probiotics You're Taking? You May Be Surprised at What I Found

I've told my readers for years to take probiotics to fight pathogenic or "bad" bacteria. I've always recommended taking various specific strains of Lactobacillus and Bifidobacteria because they are the most widely studied and distributed. Numerous studies have found them to be both safe and effective.

But now there's a new kid on the block — soil-based organisms (SBOs) — that claim to be superior. But not only is their superiority unproven ... they could contribute to major health problems!

The most common SBOs used in probiotic formulas are several species of Bacillus. The people who make and sell these formulas tout their virtues and list dozens of testimonials. But Dr. Hamilton-Miller, a medical microbiologist at a major London medical school is worried. Bacillus is not considered to be part of the normal flora in the intestines of people or animals, and some species are known to cause serious health problems. Anthrax, for instance, is a species of Bacillus.

There are more than 100 Bacillus species and they are notoriously difficult to identify. Because some species of Bacillus can be harmful, you need to know exactly which ones are in any formula you intend to take.

You should also know whether there have been long-term, double-blinded randomized studies on the safety and effectiveness of each species, published in peer-reviewed medical journals, before taking any product that contains them.

I read more than 50 studies, papers, and textbooks, and spoke with experts in the field of probiotics to research this article. I couldn't find sound studies to back up the claims for SBOs for human health anywhere!

I know that my stand on SBOs is likely to make me very

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unpopular with anyone who has read articles or ads about them. Especially since some well-known doctors have endorsed them and many people feel better after taking them. But I can't help it. If there isn't good science behind a product, I need to tell you. Then, when the science exists, I'll help you understand what it means. When I can, I'll change my opinion and give that product the green light. Unfortunately, I can't do this yet with SBOs. In fact, I'm telling my patients to avoid them completely. I'm convinced they're dangerous for some people.

Safety first

The Food and Agriculture Organization of the United Nations and the World Health Organization asks that all probiotic producers prove that any particular species they use in their products is safe. To my knowledge, this has not been done with SBOs. Often, the specific strain is not identified.

I spoke with Ted Sellers, the vice president of Life Science Products, Inc., a multi-level marketing company that sells a probiotic formula including SBOs. He's convinced they're safe. Ted is passionate about *Bacillus* based solely on its anecdotal use. His comfort level comes from his product's history and its reported long-term safety over 20 years.

He understands that some people would feel more comfortable with double-blinded studies, but is concerned that this might put probiotics under FDA scrutiny, complicating matters for some companies. At the same time, it would identify each species and strain and assure its safety. Personally, I vote for more information on safety.

Some problems with *Bacillus*

It's very possible that the people who need probiotics the most should avoid those containing SBOs. One nutrition expert I spoke with once embraced the concept and philosophy of SBOs. This expert had a change of mind after receiving numerous calls from people who complained that they became

severely sick after using them.

Each expert I interviewed had a similar change of mind. They are concerned about the lack of quality control, lack of identification of the species strain on a product's label, and lack of studies on the safety and effectiveness of these particular strains of SBOs.

Two of the most commonly used SBOs in probiotic formulas are *Bacillus subtilis* and *Bacillus licheniformis*. A paper from the Graduate School of Biomedical Sciences at the University of Texas Medical Branch states that both "are periodically associated with bacteremia/septicemia, endocarditis, meningitis, and infections or wounds, (in) the ears, eyes, respiratory tract, urinary tract, and gastrointestinal tract." Let's take a closer look at these two bacteria.

Bacillus subtilis: If you ever need to take an antibiotic, you don't want to take *B. subtilis* with it. You could cancel out any benefits from the drug. Some strains of *B. subtilis* are resistant to many antibiotics and can even cause an infection in the blood (septicemia) in people with a suppressed immune system. In one case, it contributed to a patient's death.

A man in his 70s with leukemia had been taking an Italian formula of SBOs until he was admitted to the hospital with a high fever from a bacterial infection. His condition deteriorated, and he was given a number of antibiotics. The antibiotics didn't work. His blood tests showed high levels of *B. subtilis*, and further lab tests found it was resistant to every antibiotic he had been given. Unfortunately, he died.

A group of London researchers attempted to evaluate the effectiveness of a group of SBOs. They were dismayed to find that only one-out-of-five products were correctly labeled. In most cases, the bacterium labeled *B. subtilis* was not that species at all. All were resistant to antibiotics including penicillin and ampicillin. Most microbial laboratories throw out *B. subtilis* or report it as a contaminant.

Bacillus licheniformis: Food poisoning,

Some *Bacillus* “may be problematic and should be accepted only for clearly defined strains, which have been tested negative for toxicity and pathogenicity in vitro and in vivo.”

– European Commission Health & Consumer Protection Directorate-General, updated October 17, 2002

antibiotic resistance, and infections have all been associated with this species of *Bacillus*. A group of mice with low immunity were given 13 different strains of *B. licheniformis*. Every single one of these strains caused infections in their brains and lungs.

That’s not all. A committee on animal nutrition found that one strain of *B. licheniformis* was unsafe in animal feed because it caused antibiotic resistance. A Finnish research team found that other strains caused food poisoning and infections. These scientists question the safety of *B. licheniformis* in general. A third study conducted at the University of Maryland Cancer Center on *Bacillus* infections in cancer patients concluded that these *Bacillus* species are “now being recognized as a bacterial pathogen for compromised hosts.”

Clearly, we need more studies to show which species, and strains of a species, are both safe and effective in humans. This is especially important for anyone who is sick or has low immunity. I’d like to see a number of double-blinded tests over a longer period of time with each species and strain of bacteria clearly identified. That’s what it takes to assure the public of safety.

The FDA agrees. It issued a warning letter to one company that sells SBOs. The company advertised that its products have “been shown to drastically reduce populations of yeast, parasites, and bad bacteria in the intestines.” The FDA said, prove it.

Which probiotics should you take?

There are many probiotic formulas that contain species and strains found safe and

effective in hundreds of good double-blind tests published in peer-reviewed medical journals. Each species is clearly marked on its label or in its literature so you can find the studies on that particular species. And the particular strain of the species is also identified and proven to be safe.

Don’t shy away from probiotics. Many are safe, although some are much more effective than others. A good probiotic formula can save your health — and your life.

Next month, I’ll tell you about the best probiotic formulas I’ve ever found (there are three of them) and when to use each. One of them, known to stop the deadly flesh-eating bacteria, brought a friend of mine back from imminent death. You won’t want to miss this incredible story in next month’s issue! ■

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