BUGS WITH BENEFITS?

Probiotics may not be harmless

“Promote digestive balance.” “Helps maintain a healthy immune system.” “Friendly bacteria that benefit your skin, health & beauty.”

Probiotics make appealing promises, but they may not deliver...and may not be safe.

Q: What is a probiotic?
A: According to the World Health Organization, a probiotic is a “live microorganism, which when administered in adequate amounts, confers a health benefit on the host.”

But in the United States, probiotics are foods or supplements with live microorganisms that simply claim to maintain or enhance health. Companies don’t need evidence that they do.

Q: Why not?
A: Many probiotics are supplements, which are loosely regulated by the Food and Drug Administration.

As long as companies stick to the language of the law, they can imply that a probiotic works. They just have to use something called a structure-function claim: that is, that the probiotic supports the structure or function of a body system.

Probiotics companies can’t claim to treat or cure a disease. They can’t say, for example, that their product “treats diabetes” or “lowers blood sugar.” But they can say that it “supports healthy blood sugar levels.” Most consumers will interpret those phrases to mean the same thing, so labels can be misleading.

Q: Can probiotics keep us healthy?
A: Many small, preliminary studies have looked at whether healthy people are, say, less likely to get the flu or have gastrointestinal discomfort if they take a probiotic. But the results are inconsistent. What’s missing are large, long-term, high-quality studies to see if probiotics work.

Q: What misconceptions do we have about probiotics?
A: Many people think of probiotics as interchangeables—that all these bacteria are good and you can just take anything. But that’s not true.

We should think about them like a medication. You wouldn’t take any random medication to treat high blood pressure. You’d take a drug that lowers blood pressure.

Similarly, when probiotics are helpful, it’s a very specific strain of a microorganism that you have to take.

If we find that a probiotic can help healthy people stay healthy, it will almost definitely be a very specific strain of a bacteria at a very specific dose.

Q: If there isn’t good evidence, why do so many people take probiotics?
A: Scientists have made tremendous advances in our understanding of the microbiome—the bacteria that live in our gut—and how important it is for our health.

That enthusiasm for the microbiome, along with some creative marketing and a supplement market that is so loosely regulated, has allowed this area to explode. The market has completely outpaced the science.

Q: What else confuses people?
A: People think that you can take a probiotic and it will colonize your gut and become part of your microbiome.

But there isn’t good evidence that most probiotics even take up residence in the gut if we have a healthy, intact microbiome. Most of the research supports the idea that probiotics are visitors that have some benefit as they pass through.

Can a probiotic make you feel like a warrior? Don’t count on it.

Pieter Cohen is an associate professor of medicine at Harvard Medical School and a general internist at Cambridge Health Alliance. He is an expert on—and, at times, an outspoken critic of—the dietary supplement industry. Cohen spoke with Nutrition Action’s Caitlin Dow.
Ever been told that you should load up on probiotics after a round of antibiotics? You’re not alone.

In one survey of doctors and other healthcare providers, nearly 50 percent had recently recommended probiotics for patients who were taking antibiotics. Yet “the evidence for taking probiotics after antibiotics is highly debated,” says Eran Elinav, a professor of immunology at the Weizmann Institute of Science in Israel.

Elinav gave antibiotics to 21 healthy adults for a week and then randomly assigned them to:
- get no additional treatment (the control group),
- get a fecal transplant, which was made from their own microbiome before they took the antibiotics, or
- take a probiotic for four weeks.

“We chose a multi-strain probiotic containing 11 of the most commonly used bacteria in the probiotics market,” says Elinav.

The results: The microbiomes of the control group returned to their initial composition after four weeks. But among those who got the fecal transplant, “the microbiome was no different from its original composition just one day after transplantation,” says Elinav. (That’s impressive, but fecal transplants aren’t something you can do at home.)

Most surprising were the probiotic takers. Their microbiomes didn’t return to normal.

“They also had microbiome characteristics that were suggestive of pathological states, such as low bacterial diversity and sustained microbiome imbalance,” notes Elinav.

“And those effects lasted for as long as we sampled, which was six months after the antibiotics course.”

It’s not clear what those changes mean for your health, but they’re not likely to improve it.

“Contrary to the current dogma, which says that probiotics are harmless and benefit everyone, our results point out that consumption of probiotics following antibiotics can delay the restoration of a person’s microbiome,” says Elinav.

“If our intent is to restore the microbiome to its initial state, probiotics are clearly not the preferred means to achieve it. We need high-quality studies to further assess this potentially alarming adverse effect of probiotics after antibiotic use.” —Caitlin Dow

Microbiome. Most of the research suggests that probiotics are visitors that are just passing through. They might have some benefit as they pass through, but those benefits haven’t been well-characterized.

And some probiotics may not be stored properly before or after people buy them. Some need to be refrigerated but aren’t. So they may not even be alive by the time you swallow them.

The most likely scenario is that people are wasting their money.

Q: Is that true for all probiotics?
A: No. For example, the yeast Saccharomyces boulardii reduces the risk of antibiotic-associated diarrhea. But, again, it’s a very specific probiotic for a very specific health concern.

Q: Can a doctor help patients pick the right probiotic?
A: When it comes to probiotics, many doctors are just as confused as consumers. Doctors are in the learning stage, and we need to realize that just as medications differ from one another, so do bacteria.

As the science is clarified, we’ll be recommending the right strain for the right problem, but we’re not there yet.

Q: Do probiotics pose other problems for doctors?
A: Yes. A doctor might prescribe a probiotic for good reason. Maybe they have a patient that they’re treating for Clostridium difficile—a bacterial infection that causes diarrhea and can cause serious inflammation of the colon. A probiotic like Saccharomyces boulardii may reduce the risk of C. difficile-associated diarrhea, so the doctor calls down to the hospital pharmacy and requests S. boulardii for the patient.

But the pharmacy may well not have it. A recent study found that most hospital pharmacies only stock one kind of probiotic. And it may not be the one that the patient needs.

Are Probiotics Safe?

Q: Do we know if probiotics are safe?
A: We don’t. A recent study reviewed nearly 400 randomized controlled trials aimed at changing the microbiome, usually with probiotics. Most of them didn’t adequately report adverse effects. Without that information, we can’t say whether probiotics are safe.

Q: How might probiotics cause harm?
A: In dozens of case reports, probiotics have caused infections in people who...
are frail or immune-compromised. For example, if there’s a breakdown in the lining of the gut, the probiotic bacteria can enter the bloodstream and spread throughout the body. But those are very rare situations in people who are already really sick. Generally, probiotics don’t cause infections in healthy people.

Q: So do healthy people need to worry about probiotics?
A: At this point, we’re concerned about risks that are theoretical. For example, probiotics, like all bacteria, may have genes that make them resistant to certain antibiotics. Some of these genes can hop from one bacterium to another.

So if you took a probiotic supplement with an antibiotic-resistant gene, it could transfer to a disease-causing bacteria in your gut. And then you’d have something that could be resistant to treatment.

Q: How likely is that?
A: The odds of it happening seem remote. However, it has happened in animal and test tube studies.

In the only study that’s been done in people, the gene didn’t get transferred from the probiotic that people swallowed to the bacteria in their gut. But that was done in only seven people.

We need more research to know if gene transfers can happen in the human intestine.

Q: Does anything else worry you?
A: Quality is an issue with all kinds of supplements.

The FDA has recommended “good manufacturing practices” that companies are supposed to adhere to. But of roughly 650 supplement-making facilities that the FDA inspected in 2017, roughly half had violations such as failure to accurately report the identity, purity, and strength of their supplements.

There’s also the issue of contamination. Multiple studies have found that commercial probiotics contained live—though rarely harmful—microorganisms that weren’t listed on the label. So consumers may not get what they think they’re getting.

Q: What can the FDA do to improve the quality and safety of probiotics?
A: The FDA recently released a draft guidance that would give probiotic sellers the option of listing the number of colony forming units—the number of live organisms—in a serving. The FDA should make that a requirement instead of an option.

The FDA should also require companies to list the strain or strains of bacteria in a bottle along with the number of live organisms for each strain. That’s also optional now, and it should be required.

And the FDA should update its good manufacturing practices to include safety testing that would identify and eliminate potentially transferable antibiotic-resistant genes. Plus the agency should do more inspections to ensure that there are no contaminants in probiotics.

Q: Is that realistic?
A: Canada already requires its probiotic manufacturers to adhere to these standards, so this is all doable. I’d like to see the FDA be much more aggressive in regulating and keeping a close eye on the companies that produce probiotics.

Q: Should the FDA take probiotics off the market?
A: No. We need high-quality probiotics with good safety track records that are accurately labeled and that make health claims only if there’s substantial evidence to support them.

But that would require a new law, and Congress is unlikely to tackle this topic any time soon, unfortunately.

Q: What should consumers do in the meantime?
A: I don’t recommend starting a probiotic unless you talk to your doctor first. And if your doctor recommends one, ask her or him to show you the study that supports the use of a specific strain of a probiotic for whatever condition you have. That won’t address all the issues, but it’s a good place to start.

Q: So you’d be cautious?
A: Yes. Many of the safety concerns are theoretical, but so are many of the benefits.

Consumers should appreciate that, even if probiotics can colonize your gut, you’re talking about changing your microbiome without any evidence that that’s a good idea. Despite the advertising, it’s best to be cautious and skeptical.