

Dannon Probiotics Media Briefing Transcript

Fall, 2008

Featuring Dr. W. Allan Walker, MD and Dr. Mary Ellen Sanders, PhD

Miguel Freitas:

Good morning everyone. Thank you all for coming to this seminar about understanding probiotics. This topic is of great interest for Dannon, but also for myself personally. I am a microbiologist by training. I did my Ph.D. at the equivalent of the NIH in Paris on microbiology, probiotics, and intestinal health.

Now I work for Dannon in the U.S. I'm responsible for health marketing. I'm the scientific affairs director at Dannon. And I'm responsible also for all the communications with the health care professionals in the U.S. when it comes to probiotics. At Dannon and at Danone - Danone is a parent company of Dannon - we are committed to pioneering innovations in clinical research and understanding the benefits of probiotics.

But it's very important to say that here today we don't want to talk about probiotic brands. There are brands commercialized by Dannon, but we don't want to talk about Dannon at all. This is about understanding the science behind this general topic of probiotics.

And I am very happy to have here today two of the most renowned experts in the probiotic field. Dr. Mary Ellen Sanders here on my left and Dr. Alan Walker on my right. They will be delving into specific topics including how the researchers are studying probiotics today what are the benefits of probiotics for children, for adults and for seniors, and where are we going in terms of science, what is the future of probiotics research moving forward.

Dr. Sanders and Dr. Walker will separate the facts from the myth about probiotics and will discuss the history, the present, and the future. Both Dr. Sanders and Dr. Walker are, again, experts on this field and they participate in different advisory boards for different companies including Dannon.

So very quickly, Dr. Mary Ellen Sanders will be our first speaker today. Dr. Mary Ellen Sanders of Dairy and Food Culture Technologies, who's also the executive director of the International Scientific Association for Probiotics and Prebiotics-- ISAPP. It's a non-profit-- association of scientists working to advance the science of probiotics and prebiotics. Dr. Sanders received her degree in food science at University of California at Davis and her Master and Ph.D. in food science with an emphasis in microbiology at North Carolina State University.

Dr. Alan Walker (PhD), our second speaker today, is the director of the Division of Nutrition at the Harvard Medical School. And he has a long-standing interest and commitment to nutritional research. He served for six years at the Committee of Nutrition of the American Academy of Pediatrics. He is a pediatrician by training and he received several research awards related to nutrition in the past years.

In between these two speakers, we will have questions and answers. And to help facilitate those questions and answers, we have today here Elaine MaGee. Elaine is a registered dietician, author and nutrition writer for WebMD, Silverplanet.com and she's also known as the recipe doctor in this website. Elaine graduated from Central San Jose State University with a Bachelor of Science in Nutrition and obtained her Master's in Public Health Nutrition from UC Berkeley. So, I guess, without any further delay, I will let Dr. Sanders start her talk. I guess you have some slides.

DR. MARY ELLEN SANDERS:

I do.

MIGUEL FREITAS:

And that's it. Thank you again very much.

DR. MARY ELLEN SANDERS:

I was asked to try to keep this very informal which I would definitely like to do. But I wanted to put together a few slides just to help make sure I didn't forget key points and provide a few visuals to help along the way as well.

You do not but if you would like copies of them, I can certainly e-mail you a copy of them. If you want to contact me, my e-mail address is mes@mesanders.com.

I think it's important first of all to understand what a probiotic is. And sometimes this word is misrepresented in the popular press. And so what I'd like to offer is a definition that was put together by a consensus group of scientists that were convened by the FAO/WHO back in 2001.

And the definition is that probiotics are "live microorganisms which when administered in adequate amounts confer a health benefit on the host". And it's important to recognize in our current marketing environment that there is no legal definition of the word probiotic. So right now, although there's a scientific understanding of what the word means, there is no legal definition.

And so, people can put the name or the term probiotic on products without really meeting any legally imposed criteria. I would also like to differentiate between probiotics and our native, potentially beneficial microorganisms that colonize our intestinal tract and our bodies in general.

Probiotics are often called "friendly bacteria". And certainly that's a fair characterization of them. But probiotics by definition have to be isolated and studied and shown to have an effect. And that's what really differentiates them from the normal bacteria we may have colonizing our bodies – some of which maybe good for us. But unless we've specifically studied those particular microorganisms, the term probiotic doesn't really apply. And I finally would just like to point out that there are lots of different types of microorganisms that are used as probiotics. In this country, primarily *Lactobacillus* and *Bifidobacterium* are the ones that are usually used.

So just a little crash course in bacterial nomenclature - or how these microorganisms are named. And that can help you sort of navigate what you read in different media out there. First of all, microorganisms are characterized by their genus. So in this example, two different genera would be *Lactobacillus* and *Bifidobacterium*.

In addition to identifying the genus, you also identify the species of the organism. And different species of each of these genera are used as probiotics. So, for example, within the *Lactobacillus* genus, *Lactobacillus acidophilus* and *Lactobacillus casei* are examples of two different species. But what makes it even more complicated is that within the same species of microorganism, there are even different strains.

And so, the example I use here are two different strains of *Lactobacillus acidophilus*. One of them is NCFM, the other is LA-1. Both of these have been studied as probiotic organisms and have different types of substantiating evidence for health effects.

A point that oftentimes is lost is that even different strains of the same species can have different probiotic effects. And so it's important to be able to identify these microorganisms, really down to the strain level. And the example I like to use to try to drive this point home is differences between different breeds of horses. All of these animals are the same species, but you can see that within each breed, they each have different characteristics and different strengths, and you'd use them for different purposes.

And that's the same kind of situation that analogous to the situation with probiotic bacteria. So even though they're the same species, they have different functions as individuals.

The next point I would like to make is to differentiate the concept of live cultures, which is a very consumer friendly term, from the concept of probiotics.

Oftentimes the term live cultures is used to be synonymous with probiotics. But that's not really precise. Live cultures are microbes that are used to make fermented foods. There are many examples of fermented foods on this picture here.

But cheese, cultured cottage cheese, yogurt, vegetables, meat, beer, bread, wine are all fermented foods that exist because the microbes make some transformation of the food to make that final food product. In some of these foods, primarily fermented dairy products, these products are sold in a form where the microorganisms are alive.

But many of these products are somehow processed so the microorganisms are killed or removed. For example, usually yeast is filtered out of beer and oftentimes fermented vegetables are pasteurized before they're sold. But in many fermented dairy products, there are live active cultures. And those products are legitimate sources of live cultures. But are those products necessarily probiotic products?

The key point here is that because the specific definition of probiotics requires that these organisms be tested and shown to have particular health benefits, the live cultures cannot be considered probiotic unless they've gone through that rigorous testing for health benefits. So, it's fine to say that these products are sources of live cultures. But if they haven't been studied and aren't tied to clinical benefits, then it's really not appropriate to use the term "probiotic" to describe them. What makes it a bit confusing is that those "live cultures" *may* have health benefits – but again, unless those health benefits are documented, you shouldn't use the term "probiotic" to describe them.

Another very common question we run into, and it's an important one to communicate to consumers, is about the dose or the levels of these probiotic bacteria that are needed to impart a health benefit. I really wish I could give you one number – one magic dose – that you could just report for that. I wish I could say that as long as you have one billion per serving, you'll be able to be fine regardless of what the product is.

But that is just unfortunately not the case. Each probiotic, and again think back to the fact that these effects are strain-specific, each probiotic has been tested at a particular dose or range of doses. So really the only science-based approach to be able to answer the question of how many are needed is to say the number needed is the number that has been shown to be effective in clinical studies.

And that number may vary quite broadly. For example, there are two probiotics that are currently on the market that have been tested at a hundred million per day. A hundred million what are called CFU or Colony Forming Units, which is a measure of live bacteria.

100 million CFU is on the low side, I think, of what many people probably think is an appropriate dose. Yet another product, VSL3, which is a combination of eight different live microorganisms is actually studied at 1.8 trillion CFU/day, so over one trillion live microbes per day. This amounts to a four order of magnitude difference between recommended doses for these products.

These are huge differences. And so, as much as you want to be able to say, "well, just pick a product that has x number of microorganisms in it," that's really not scientifically precise in terms of how you have to go about determining if these microbes are being delivered in an adequate dose.

QUESTION:

Okay. I have a question. I mean, from the consumer's standpoint, people don't necessarily know a lot about these products in terms of the science of it. Now, as an individual, people's bodies are different. Your body's different on any given day that you get up. How do you know what dose of these things are good for you? Or if you even need it? You might be throwing your system out of balance. You know what I mean? It's kind of hard to know what you're taking and how that will benefit you. And then how long do you take a product, when do you stop? If your body's supposed to be in balance, you don't want to throw it out of balance.

DR. MARY ELLEN SANDERS:

You're touching on so many different issues here, but that's a very excellent question. First of all, I'd like to just address the balance issue. The microorganisms that you consume in these products do survive intestinal transit. Most legitimate probiotic products have been shown to survive intestinal transit and make it to the colon alive. That's true.

But the numbers that you're consuming in comparison to the numbers of microbes that are already there is really fairly small. You've got trillions of microorganisms that are colonizing your body. So, even though we like to think that consuming these microorganisms is really improving the balance of microbes, they're really not capable of shifting those populations in a big degree.

People are fairly stably colonized by the microbes that are associated with their bodies. To answer your question about how does a consumer know if they want to take them, I really think there's probably two different paths that consumers are on. One is they have something very specific that they want to address and they've heard that probiotics might address some of those issues.

So, for example, people who are on antibiotics or might have mild symptoms of irritable bowel syndrome may have a very specific purpose that they're looking for a probiotic to help them cope with. And in that case, they'll know if it works or not. And they are compelled to choose a product that has been tested for those effect.

QUESTION:

Within a two to four week period would you say?

DR. MARY ELLEN SANDERS:

That's a good point. Usually you do have to give these organisms a while to be able to do what they do. It's not an immediate response, it's not an hour later you're going to notice the difference.

QUESTION:

Okay. And then I mean, as soon as you start to feel better, then you don't need them anymore?

DR. MARY ELLEN SANDERS:

Many times we don't have the precise studies to answer this question exactly - how long does it take and how long do we need to consume them? But I know that benefits can be sustained over time. So studies that have been done with mild irritable bowel syndrome symptoms for example, at week one they may show a benefit. At week two they continue to show the benefit. At week three they continue. Then you stop the study say after four weeks and the benefit starts to wane. So if you want the benefit sustained, you do have to continue taking them.

DR. MARY ELLEN SANDERS:

You know, the other person or type of consumer that might be interested in these products might be one that's really looking at trying to enhance and, sort of, structure their diet in the best possible way. And they know that these microbes have been shown to have some effects, for example, on immune function or other types of maybe more difficult-to-see endpoints.

But that's one of the reasons I like the probiotic foods. Instead of really looking at them as a specific pill to solve a problem, you're looking at structuring your diet in a healthy way that will incorporate these products that may give you a benefit of staying healthier, of not getting sick quite as often. But that's a little less of an obvious endpoint for people in many cases.

DR. MARY ELLEN SANDERS:

I hope that answered your question. So the dose really needs to be tied to the specific clinical studies and hopefully, any of the responsible manufacturers will make sure that any products they market contain the dose that matches the clinical studies.

So just very briefly, when a company wants to go out and isolate and identify a probiotic, what is it that they do? Generally speaking, they isolate it from either intestinal mucosal tissue, or from a healthy person, or from fecal samples. One commercial strain was isolated from breast milk. There have been different ones isolated from different animal species. So, they find a microorganism that for one reason or another they think is going to bring the physiological characteristics that they want up out of a probiotic.

They have to isolate and identify the microorganism using all the modern techniques that are available to them. They have to ask if it's a good candidate for being a probiotic. And to do that, they launch research that's really what we call at the pre-clinical level. Which is doing characterizations in the laboratories and potentially even in animal models.

Then they have to ask, is it safe? Are there any concerns for the generally healthy population for consuming large numbers of these live microorganisms. Then they ask - is it efficacious? And that includes launching human clinical studies. And these studies really should be published and peer reviewed and available to the public to read. And then, finally, they have to construct a product - that is appropriately labeled - to sell in the market.

I'd like to just take a second to talk about what those labels might say. There again are no legal requirements for any of these characteristics on a product label. But this is my interpretation and opinion about what these labels should contain. To properly communicate what's in your product, the genus, species, and strain for each probiotic strain in the product should be listed.

The level of each of the strains in the product through the end of shelf-life should be listed. And I will caution you that there are some dietary supplement products that are labeled with counts at time of manufacture. But, of course, these microorganisms can die over time. And so indicated the levels in the product at the time of manufacture is not a very relevant or useful piece of information to give to a consumer. More relevant is how many are going to be there at the end of shelf-life. Which you know, might be the dose that you're actually taking.

The label should also tell you what serving sizes or dose if it's a dietary supplement, how many pills or capsules you might need to take per day. How to store the product. When we're talking about foods, at least fermented dairy foods, those are essentially refrigerated products, but many of the supplements stored at room temperature. But, some of them are refrigerated. And also where to get additional information where you can link the product to the clinical substantiation should be available on the web.

QUESTION:

Just to clarify, these are being sold as drugs in any way? Because you're talking about efficacy and safety like you would in a clinical trial for a drug, but these are not regulated by the FDA or the USDA as far as what they're actually doing?

DR. MARY ELLEN SANDERS:

In the United States there's only two categories of products that contain probiotics for humans, they are foods and dietary supplements. And legally, dietary supplements are a category of foods. So you're exactly right, these are not drugs. So these are not intended to cure, treat, prevent, mitigate, or diagnose disease which is the legal definition of a drug.

I will say that although dietary supplements in foods are often categorized as not being regulated by the FDA, the FDA in fact does regulate these. They are not subjected to "pre-market" approval, but they are regulated. The FDA requires that these products are safe, and they need to be labeled in a truthful and not misleading fashion.

Now where the FDA falls short is enforcing these regulations. And so as long as you're not trying to label a dietary supplement or a food in a fashion that would be interpreted as a drug by the FDA, they tend to not ask to see your clinical substantiation which supports the accuracy of the claims being made.

So that's where the gap really exists in the current marketplace. Then oftentimes people will say, well, "What's better? Probiotic food or probiotic supplement?" Because again both of these categories are currently available. I would say that in terms of the state of the information we have today, it's probably more important to pick a quality product that meets your specific needs, than it is to necessarily worry about whether it's a food or dietary supplement.

If someone with antibiotic associated side-effect issues wants to take a probiotic to address that, they would be better advised to ask which products specifically have been tested and shown to be effective for antibiotic associated side-effects, and take that rather than say, "You know, I really want a particular yogurt, or a particular type of pill."

So really it gets tied to the product benefits and the label needs to give the appropriate information on the types of benefits the product has.

I think really it comes down to consumers buying from a company that they trust. A trustworthy manufacturer who's got a good track record and appropriate communications to consumers is a good choice. But consumers must also choose a product in a format that they will use. And as was mentioned, often times these products need to be consumed over time. And so, it's not just a function of taking one pill and being able to stop.

So if you're not a pill taker, or consistently able to add pills into your routine, then a food choice is a good one. The other comment that can be made is that at least in the case of a food, you're also getting the nutritional elements that the food provides along with the probiotics. And so-- it's a nice addition to a healthy diet, as opposed to a pill which is pretty much giving you what's in the pill.

QUESTION:

All right. How about interactions. I mean, in terms of when you take certain things, there are certain, let's say, medicines that you shouldn't take with certain foods. How are probiotics targeted like that?

DR. MARY ELLEN SANDERS:

I'm not aware of any interaction issues that you need to be concerned about in terms of probiotics. Often times they'll say to take probiotics with foods because it can help neutralize the stomach acid. So if you're taking a pill, maybe taking it with a glass of milk or with a yogurt could help make it so it can survive the stomach a little bit easier.

But even those studies have not been rigorously done. We know that the stomach can cause some of these microbes to die, but it doesn't necessarily mean that it makes the product ineffective.

DR. ALAN WALKER:

There are actually certain clinical conditions where it's a little dangerous to take probiotics. And so, one has to be aware of those before one makes a recommendation. What Mary Ellen was talking about is the general public, principally healthy, of if they have a minor problem, it's okay.

Now with regard to stomach acid, if you're taking medication to reduce the stomach acid because of regurgitation or whatever, you can actually allow not only probiotics but other bacteria to get in and very often there are intestinal problems that exist in individuals who take the medication. There's now some strong evidence that suggests that you should take an antacid for that reason. It helps to protect against intestinal gastroenteritis that you get because you've lost the protection of the stomach acid.

QUESTION:

So by regurgitation you mean acid reflux?

DR. ALAN WALKER:

Yeah.

QUESTION:

Gerd?

DR. ALAN WALKER:

A lot of people have that.

QUESTION:

They're common.

DR. ALAN WALKER:

And the medications that they call H2 blockers that knock out the acid in the stomach it's almost as common as Lipitor. Some of the medications that everybody in the country takes. So this is a problem.

QUESTION:

Would that include the proton pump inhibitors too?

DR. ALAN WALKER:

Yup.

QUESTION:

So the H2 blockers and the proton pump inhibitors which are common medications for people with GERD or acid reflux. So you're saying now that it looks like there might be a case for probiotics being used in conjunction with these medications.

DR. ALAN WALKER:

There's new evidence that if you take these antacids you have a higher incidence of bacterial and viral gastroenteritis because the stomach protection when you swallow things that have organisms isn't there. And so that people are now suggesting and there are studies that are starting to come out that show that this may reduce the number of instances of gastroenteritis if you take a probiotic with an antacid.

QUESTION:

So will you actually need a problem to take probiotics? Because I feel like probiotics is a new buzzword like organic, and now it's just something that you see on a label and you just take it because it's generally healthy. And you're talking of how there's no legal definition, so can your average consumer's just going to buy something with yogurt that says "with probiotics" and your going say that's healthy in general.

DR. MARY ELLEN SANDERS:

I would never say that a generally healthy person needs a probiotic because we certainly have a lot of healthy people out there who are not taking probiotics. But there's mounting evidence that shows, that healthy subjects can benefit from probiotics. For example, children in daycare centers have experienced modestly reduced incidences of common infectious diseases. So, do you need probiotics in an absolute sense? No. The generally healthy population does not. But can it add a layer of defense as part of a healthy diet? Yes.

QUESTION:

So even if you don't have irritable bowel syndrome, you can still take probiotics?

DR. MARY ELLEN SANDERS:

Right. And so that's sort of that second track of person that I'm talking about a - potential consumer who maybe doesn't have any specific health concern but is really interested in optimizing their diet.

And, of course, if you're choosing a yogurt and you have several options, you can choose a yogurt that not only gives you the calcium and the protein and the other nutrients that are good to have in your diet anyway, but in addition to that, you can gain the benefits of the probiotics.

QUESTION:

All right. But let's say you don't need it. You're part of that generally healthy public, and you take it, can it harm you?

DR. MARY ELLEN SANDERS:

Well, again, for the generally healthy population, the probiotics that are in foods are primarily *Lactobacillus* and *Bifidobacterium* and they have an incredibly good safety record for the generally healthy population. There have been a few cases of people with severe underlying diseases that have had problems with taking probiotics. But, you know, that's really not who we're talking about right now. That's really a medical use of them.

I was asked to kind of briefly talk about what a prebiotic is. And you have heard this term probably as well. Prebiotics are different from probiotics, but they're often times lumped into the same category because they both have an impact on the intestinal tract and intestinal health.

A prebiotic is essentially food for your native beneficial bacteria. Typically these are food ingredients that are non-digestible carbohydrates. They often meet the definition of dietary fiber. And they are metabolized selectively by members of the native bacteria that you have already in your system. They encourage the growth or the activities of these potentially beneficial bacteria. So a probiotic is alive and it's the actual microorganism. A prebiotic is really the food for your native potentially beneficial bacteria.

QUESTION:

Is there any advantage to taking prebiotics with probiotics at the same time?

DR. MARY ELLEN SANDERS:

They really are going to have different functions even though they are related functions. They will be different. And so, you can certainly take them together, but there's no requirement that if you are going to take a prebiotic it's taken at the same time as the probiotic that you might be consuming as well.

Some products do actually mix them together and those are called symbiotic products.

Not all products that call themselves probiotics are probiotics, and that's really a difficult issue for the consumer. The consumer is not always well-equipped to differentiate between products that are truly using the word properly and ones that are just sort of capitalizing on the buzzword. There are certainly products that don't have any clinical validation that are on the market. Another important point is not all probiotics are the same. Different probiotics can have different health benefits.

Again, one dose does not fit for all products. The potency or what you deliver in a probiotic serving or dose of food should be based on the human studies that document the health benefits that are being claimed on the product.

The labels have to provide useful information, I mentioned them before. Finally, I think good advice to consumers is they have to purchase from a trusted manufacturer. So I will stop there, and if there are questions I'd be happy to answer them.

ELAINE MAGEE:

Yeah, we've got about five minutes for some questions until we go on to Dr. Walker.

QUESTION:

I'm just curious, there are in this supplement form the probiotic would be dry. What is the difference between the dry strain and the wet strain that you're going to get in something like cheese or in yogurt, and how does the dry strain get activated?

DR. MARY ELLEN SANDERS:

Well, a dry strain is sort of in a state of suspended animation. Some people think that once it's dried it's not alive anymore, and that's not true. You can certainly recover live bacteria at very high numbers from dried products.

QUESTION:

So it would be more like a dormancy?

DR. MARY ELLEN SANDERS:

It is a dormant state, and when it hits the moisture, it reactivates and it can start metabolizing and growing again. We often times don't have good controlled studies since the intestinal tract is not an easy system to study.

But what I can say is that there are many, many published clinical studies with supplements in dried form that show effects. And so, there's nothing about the dried format that would make you say it's not allowing the product to work.

QUESTION:

So is that what they're using in the cereals that they're advertising?

DR. MARY ELLEN SANDERS:

Probably. Yep. Some kind of dried format. That's exactly what I think it is. But you're absolutely right. You're touching on a very important research area right now which is understanding the difference between a microorganism that's allowed to grow, allowed to metabolize in one type of environment compared to ones that aren't. Are their differences when what you're consuming is not just a probiotic organism but also fermentation by-products and other things that are part of that whole functional food? But we just don't have the research quite yet to very specifically say how probiotics might differ when delivered or made in different products.

QUESTION:

Do we know whether there's an advantage in terms of stomach acid and consuming it in the wet food versus the supplement in the dried form and the stomach acid?

DR. MARY ELLEN SANDERS:

Clearly if you take a pill with a little swallow of water on an empty stomach, it's gonna be hitting an environment that's much harsher than if you have a glass of milk or you eat yogurt with a probiotic in it. And so that certainly is something to consider.

But again, studies have been conducted showing that those dried products do have effects. So I don't want to say that even if they do run into some survival challenges in the stomach that it completely negates their ability to do what they need to do.

QUESTION:

What are some of the diseases and conditions for which probiotics are contraindicated?

DR. ALAN WALKER:

What happens is when you take a probiotic, it's a live organism which is by definition not very dangerous unless your body can't handle defenses against normal live organisms. So, if you have someone who's on chemotherapy, or if you have someone whose immune system has been disrupted for some reason, and you're very cautious about giving that individual a live organism. With the general public, it's probably never gonna cause a problem, or very, very rarely cause a problem. I think it would be just something that has to be decided medically that would not be indicated for use of probiotics.

QUESTION:

There was recent study, a Dutch study with acute pancreatitis, anything else you've recently seen besides that one?

DR. ALAN WALKER:

There have been a number of studies with immune deficiencies. And that particular study, they were using probiotics to study patients who have pancreatitis. Pancreatitis causes inflammation of the pancreas, but also disrupts the surface of the intestine so it's more permeable to bacteria. And what they found is they had a much higher incidence of death in those given probiotics than not. But pancreatitis itself is a fulminate disease.

QUESTION:

Yeah.

DR. ALAN WALKER:

So you have a lot of deaths that way, so.

QUESTION:

Yeah.

DR. ALAN WALKER:

It was now thought to be contraindicated.

ELAINE MAGEE:

Another question? Oh, two questions.

QUESTION:

What about people with AIDS when you're saying compromised immune system, would that include people with AIDS or not?

DR. ALAN WALKER:

That's a very good question. As you know, people with AIDS have an acquired immune deficiency. So theoretically, they shouldn't be given probiotics. On the other hand, they frequently die from bacteria in the gut in the blood stream causing sepsis. And so, probiotics are very effective in preventing that. So there's kind of a controversy. It's certainly is not something that you would routinely recommend. This would be something they'd have to do through a medical recommendation.

ELAINE MAGEE:

Was that your question?

QUESTION:

Yeah, that was it.

ELAINE MAGEE:

Okay. One last question. As journalists, what do we need to know to be able to evaluate some of the science about probiotics as it continues to come out? I'm guessing we'll see a lot more in the future. So what should we look at when we see some of these studies?

DR. MARY ELLEN SANDERS:

Of course, it's always difficult to make recommendations based on a single study. So I think as journalists you need to look at totality of evidence. What does the body of evidence say? But having said that, sometimes there are some really neat studies that get published that really make you say, "You know, this is probably a good indication."

ELAINE MAGEE:

Exactly.

DR. ALAN WALKER:

Just as what Mary Ellen said is absolutely correct. There's a lot of misuse of probiotics by manufacturers that falls into the functional food category. And as Mary Ellen said, it's not as well regulated as drugs are.

And what happens is very often someone puts a bacteria into something and calls it a probiotic. There's never been any clinical studies to show its efficacy. So what you need to know is this particular probiotic that's on the label been shown clinically to be effective against whatever it's gonna be used for. As opposed to just throwing all probiotics into the same category, very much like we used to with antibiotics. Antibiotics we know now have very specific functions. We don't use penicillin for a gram negative organism. We use another antibiotic. The same thing is now happening to probiotics.

DR. MARY ELLEN SANDERS:

And Alan brings up a good point about how some studies fail to define the organism being used: the genus, the species, and the strain. And a well-conducted study won't just say, well, we tested yogurt, we threw it in with no characterization of the microbiological components that are in there. Yogurts are great to study, but they need to be defined.

QUESTION:

I see sort of an explosion of these supplements with, you know, a million probiotics. No, a trillion, no, a gazillion you know, whatever. There doesn't appear to be like a, you know, necessary daily amount, or sort of teasing out which one's work for whatever. And so I think people just figure more is better. And so, my question is how do you decide if it's worth taking it and what amount?

DR. MARY ELLEN SANDERS:

It's so hard--

QUESTION:

--it just seems, like, mysterious.

DR. MARY ELLEN SANDERS:

It really is difficult. And I did put together a table. Did it get into the packets?

ELAINE MAGEE:

Yes, we're gonna give you an information packet on your way out. And it includes the table

DR. MARY ELLEN SANDERS:

Okay. That available on a Web site that I'm involved in: www.usprobiotics.org. It is a website that I develop the content for. And it's available in updated versions as time goes on

ELAINE MAGEE:

But you have the latest version--

DR. MARY ELLEN SANDERS:

You have the latest version--

ELAINE MAGEE:

--in your packet. It's exciting to me as a journalist because it has the products and what probiotics they contain. And it also has the medical or health effect.

DR. MARY ELLEN SANDERS:

This table provides a list of probiotics products based on what type of indication they've been studied for. And you'll notice it's not a very long table. And if you go to health food stores, you'll see dozens and dozens of different brands of different products. Those products may have an effect.

They may have what they claim on the label. They may, you know, be great microorganisms, but for the most part, it's very difficult to tie many of those products to specific clinical studies. You'll pick up a product and it'll say contains *Lactobacillus Acidophilus*. But, the strain isn't identified.

What you often find is that commercial products offer no scientific validation for their specific formulation. If you go chase the paper trail that the manufacturer provides, they say, "Yeah, we have a great product, and it will do all these things." And what they're referencing are review articles in the field, or a study that was done on a similar microbe, or possibly even the same species, but a different strain. They don't have that same microbe in their product at all.

And that's really why you have to go with science-based companies that really are formulating their products based on clinical studies. And that weeds that list down quite extensively. Now, I'm not saying that what I've put together has every validated product in it, because as I just said, sometimes it's hard to find how the science ties back to a commercial product.

But a company should be able to answer that question. If you really like a particular manufacturer, it should be able to tell you what studies have been done on the specific product as marketed

ELAINE MAGEE:

On that website, www.usprobiotics.org, I noticed Dr. Sanders also comments on some of the recent studies that have been published and I found that real helpful too. Just so know, that's there for you.

DR. ALAN WALKER:

Because the public is so much into the internet, that I think one way you can suggest to them is exactly what Mary Ellen said. If it's a reputable probiotic, then it's likely they'll have a Web site which supports the reason for putting the probiotic, whether it's a tablet. And if they don't have that, then the chances are very good there isn't evidence for that specific strain of organism to cause that to be used for that purpose.

ELAINE MAGEE:

Dr. Walker, I think it's time for you to....

DR. ALAN WALKER:

Okay.

DR. ALAN WALKER:

Mary Ellen had a beautiful overview. I'm just going to make some comments. And I'm happy to answer questions as we go along because my understanding is this is really an interaction, it's not a formal gathering.

I was asked to give you a little background in terms of history. If you go to Europe or you go to Asia, people for centuries have been eating fermented foods. It wasn't until the beginning of the 20th century that the term and the concept of probiotics evolved.

It was principally ascribed to an investigator at the Pasteur Institute who happened to have won a Nobel Prize for things other than probiotics, but he wrote a thesis in the early 1900s stating that individuals who eat fermented foods are likely to live longer and healthier. So this man is Eli Metchnikoff, and he's thought to be the father of probiotics.

The Japanese, as I said, the Asians have used fermented foods for a long time. The Japanese were the first to put together a yogurt. In 1936, a physician microbiologist Dr. Shirota put a lactobacillus strain into milk and that was thought to be the first probiotic strain in a food product. It's come a long way. And the field of probiotics falls into this ever-expanding area of functional foods, which has good things and bad things.

Good things – It's a more natural way to deal with problems that have failed in the general medical profession. The bad thing – there's a lot of charlatans out there (as Mary Ellen mentioned to you) who are riding the wave and calling things probiotics without adequate information.

Now, my interest in the field comes from my having trained in pediatrics and immunology. I'm very interested in how babies develop defenses against certain diseases, they develop uniquely during infancy. So we've looked at a number of things. I've spent a lot of time looking at components of breast milk and how it protects. And I should say as an aside, the whole concept of prebiotics comes from the large amount of non-digestible saccharides that exist in human milk that mother's give their babies that stimulate a different type of bacterial colonization in breast-fed versus formula-fed infants. So that the whole business with prebiotics.

Now the question is why are we interested in prebiotics? We know from the last several decades that colonization of the intestine is an incredibly important extra-uterine act allowing babies to adjust to the external environment and prevent them from developing disease. When a baby is born in a natural way, the baby picks up a lot of bacteria as he/she goes through the birth canal.

If the baby is formula-fed or breast-fed it produces a different flora -- and then it goes on to about age two when everybody has unique flora. Your flora in the intestine differs from mine because it's somewhat genetically controlled.

But what happens by age two is you have about a thousand species of organisms, and as Mary Ellen said, you have that large number, in fact you have ten times more bacteria in your intestine than you have cells in your body. So there's a lot of bacteria there.

And what happens is by age -- about 18 months to two years -- babies develop a balanced colonization and there's no expression of disease. If you have an imbalance, that is if you get more pathogens than health-promoting bacteria, then you express disease. That's why babies who go to daycare centers need things like probiotics because that balance is disrupted...because they're constantly being exposed to bacteria and other organisms within the daycare center.

And absolutely true also, the other end of the age spectrum, with elderly people who go to institutions, care centers, where they're exposed to all kinds of organisms. They too need a little boost to balance the process. The other reason from a medical perspective why probiotics have become so popular is in the last several decades, you probably have seen this in your own lives.

There's a huge increase in allergy and auto-immune disease, for example -- type one diabetes. And that's occurred in developed countries over the last 45 or 50 years. The theory for that is as we've eradicated infections by using sterile water, polluted water, vaccinations, antibiotics, we've shifted disease expression from infectious to immune-mediated disease.

And the hygiene hypothesis, have you heard of that? That's a very common entity that helps to explain this by suggesting that these public health measure, in addition to some other practices, have resulted in an inability for the intestine to develop bacterial flora properly, and therefore you get disease.

And there's a wonderful study done in Germany where they looked at allergic disease in children who were born on farms, where they had farm animals, lots of exposure to bacteria, versus children raised in the city without siblings and without pets where they had very little exposure. The incidence of allergy was much higher in those children raised in a fairly sterile environment.

Finland is probably the cleanest country in the world, it has the highest incidence of allergy and type one diabetes. So I mean, these are just examples of how changing society for the good leads to other bad things. The other thing that happens in our country is that more and more women are being delivered by Caesarian section. I'd say about 25 percent of deliveries now are by Caesarian section. The baby comes, it's delivered by Caesarian section, it doesn't get that initial bolus of bacteria as it passes through the birth canal. Babies from allergic mothers who are born by Caesarian section have a ten-fold greater incidents of allergy than those who are born naturally.

So we need to use things to balance bacteria. And there are studies that suggest that if a child is born by Caesarian section and put on probiotics, this could help. I can give you a series of two: my daughter and my daughter-in-law both had children by Caesarian section. My daughter had a history of allergies. I put the babies on a probiotic and thus far, it's not a big series, but in my personal experience it has worked out.

So it can be done. The other thing is -- there's been abuse of use of antibiotics. Antibiotics are very important for the right reason. But doctors unfortunately tend to overuse them, and one area where they do is to give babies antibiotics at the time of birth. And this disrupts that colonization process. So again, they're imbalanced and they're at much higher incidence of things like allergy and auto-immune disease.

I think some of the questions have come up about how can probiotics be used. Well, I think there are two ways of using them. And this comes back to your question. I take a multivitamin every day. I have no way of knowing what effect it has, but I know from large epidemiologic studies that at least it will balance certain things out. I may not need it, but it's sort of an insurance policy.

In some way, taking yogurt or probiotics per day has the same sort of effect. You don't have an absolute indication, but you know from studies that have been done that it's effective in helping maintain the immune system. However, in pediatrics particularly, there have been some excellent studies to suggest that probiotics may be very helpful.

Mary Ellen already mentioned a study, and there have been several in daycare centers. Babies who were started when they go to daycare on either fermented milk or a supplement, dietary supplement, have lower incidence of respiratory illness, diarrhea, and had less use of antibiotics in parents, which is very important, missed less work by having to take their sick child home. That's an important area.

But in addition to that in pediatrics, good evidence has suggested if a child develops a gastroenteritis, usually viral gastroenteritis, which if any of you have little children, almost invariably happens every winter, if you start them on a specific probiotic, it'll be less severe and last less period of time. They're not very good studies, although there are some to suggest that if you're going through a period where babies are going to be getting viral infections, you give them probiotics and that may be protective. That's not as strong as evidence as treatment.

Mary Ellen talked about antibiotic-induced diarrhea, about 25 percent of individuals who take antibiotics had diarrhea because antibiotic not only treats what it's being given for, but it disrupts the balance of flora in the gut and the pathogens take over. There are good studies that suggest that probiotics -- others who have allergy history given in utero to the mother continued with the mother while she breast feeds will cause a much lower incidence of allergy.

So it seems like there are instances in which the use of probiotics can help resolve in a better balance. Now, my interest is basic. We do a lot of laboratory studies. Looking at mechanisms by which probiotics affect the intestine. I'll give you an example. There's a fulminant condition that occurs in premature infants called necrotizing enterocolitis. About 15 percent of babies under a certain weight develop this. This is a fulminant problem, can cause death, can cause resection of intestine, the babies don't develop very well.

So we have to find ways to deal with them. There have been a number of studies where probiotics have been given to these weight babies and seem to affect a reduction in the severity of disease. We took a case from Taiwan, we took the two probiotics that were used that showed an affect in babies. We looked at them in the laboratory and we have, in our laboratory, we can grow human fetal intestinal cells. We can take therapeutically aborted fetuses, transplant them into a system where we can maintain them, just like what happens in utero.

We show that those probiotics secreted products that interacted with the immature intestinal genetic system on inflammation, lowered the inflammatory response. So we reversed it. Normally you do that first and then you do the study. But I think we've shown that there's a specific mechanism.

I use that as an illustration because there's enormous research going on across the country in how bacteria communicate with the intestine. As we find out new information, there may be new uses for probiotics or there may be new probiotics that have been identified. And also, incidentally is effective in adults. Antibiotic-induced diarrhea in adults is a problem. Probiotics have been effective.

Major problem in adults, usually in hospitalized adults is a condition called pseudo membranous colitis. It's produced by an organism called *Clostridia difficile*, produces a toxin. What happens is patients are treated, they improve, they stop the antibiotic and it comes back. They've shown that if they use probiotics with the antibiotic or right after the antibiotic has been stopped, then they don't get a recurrence. Now that saves a huge amount of expense of people having prolonged hospitalizations. And it's a significant problem.

I'm a pediatrician so I'm interested in early life. But in later life, you're immune defenses drop off, the nature of the bacteria in your intestine kind of falls off, and there's some studies that suggest that giving elderly individuals,

particularly institutionalized elderly individuals, probiotics may be effective in preventing them picking up illnesses particularly for institutions.

QUESTION:

This is what I don't understand: I can picture probiotics helping illnesses that are part of the G.I. tract, but I think I hear you saying they can also help illnesses that are part of other systems, like prevent infections in the bladder or the allergies. etc. That's the connection I don't really understand.

DR. ALAN WALKER:

It's a very good question. Very appropriate. You're right, probiotics function principally within the gastrointestinal tract. With the gastrointestinal tract is the largest immune organ in the body. So by activating that immune organ, not only can it prevent conditions within the intestine itself, but it could also prevent systemic immune mediated conditions, like auto-immune disease.

I have a good friend in Paris who's an immunologist and very interested in type one diabetes. Experimentally he has shown that using probiotics in an animal model that's prone to type one diabetes can actually interfere with the expression of the disease. So by activating the immune system in the intestine, it works both locally and comprehensively or systemically. And that's probably the case. Does that answer your question?

QUESTION:

Sort of, I mean, there was something that you were talking about...that ongoing research was explaining the relationship between the bacteria and the illness, and maybe this stuff that bacteria...passes through the intestine and goes into the blood stream?

DR. ALAN WALKER:

No. What happens very often, because there are so many organisms in the intestine, if you're healthy, things are stable. But if you're unhealthy for a variety of reasons, these bacteria can cross the intestine, get into the blood stream and cause disease. Many post-operative patients – because there's a disruption of the intestine can develop what they call sepsis, which is the infection of the blood stream from organisms that are in the gut. So that's why the gut is so important – because it's a major immune organ in the body.

So I think-- I think that's the explanation that exists.

DR. MARY ELLEN SANDERS:

Can I just add one comment? Because I'm not an immunologist I understand that these things are hard to conceptualize. But one of the pieces of information that I've recently come across is the fact that immune cells called dendritic cells can actually reach into the lumen of the gut and sample what's passing through, and it senses what's there, including the bacteria and other things. And that interaction causes it to turn something on, allows it to react. And it goes back in and it gets transmitted to the immune cells that are circulating throughout your body. And that's what Dr. Walker means -- the systemic immune system.

And so by sampling and interacting with the gut immune, it's actually signaling these immune cells through different ways of sensing what's going on in the gut. And then it starts circulating around and bringing this information to other organs in your body.

DR. ALAN WALKER:

That's a very good point. This is sophisticated immunology. But what happens is, if you don't have bacteria in the intestine, you don't stimulate the immune system so that it won't cause reactions to innocuous things getting across. And therefore you get auto-immune disease.

So it's exactly what Mary Ellen said, dendritic cells have little appendages that pass through the enterocyte into the lumen, sample colonizing bacteria, turn on its number or molecules, which then affect immune system to down regulate responses that can cause auto-immune disease. So that's another explanation for why the gut is important systemically.

The other point I should make -- there is evidence that suggests that probiotics can act to stimulate an immune response to vaccinations. There was a study done, normal healthy individuals going to a developing country that needed a typhoid vaccine. Half of them were given a probiotic for two weeks and then the vaccination. The other half, a placebo and the vaccination.

They then measured their antibody responses. Much greater in those who had been primed probiotic. And that's another potential explanation for why you'd take it on a daily basis, just to keep your immune system functioning in an optimal way. And there's one other area that you probably have heard about, but I just wanted to touch on. We're now able to measure through very sophisticated molecular techniques what bacteria exist in the intestine.

We used to have to culture it, and some of these organisms we didn't have cultures for. Now we can tell that there are 500 to 1,000 organisms. We can look at it in the context of different individuals. I mentioned earlier, everybody has a unique flora which is genetically based. However, they're now showing that in certain conditions, the nature of bacterial flora changes. And the most striking example -- studies were done in St. Louis where we looked at people who were obese, and they looked at the flora of their intestine compared to individuals who were not obese.

Same setting, and they found a different flora existed...that the bacteria in obese individuals who metabolized these foods (that Mary Ellen mentioned) aren't absorbed. They get into the colon, break them down into food substances that can come across the intestine so more calories were being developed. Now, they haven't proven that that's the basis for the obesity, but it may be contributing to it.

This has also been looked at in a condition called inflammatory bowel disease which is a very common condition, and allergy. So we're now starting to look at: Is there something about the bacterial flora that differs in these individuals? Is it a cause-effect, or is it just the incidental association?

And then finally, I just wanted to talk a little bit about future of probiotics. If you take home no message other than this, then you're ahead of the game. Probiotics function on an individualized basis. So you cannot use probiotics for everything. And that's where the health food stores and the disreputable manufacturers get a lot of action. Because they just say "probiotic," there's no basis in fact, and as we talked about before, you need to see if a specific microorganism has been used as a probiotic and its effect.

Now there are two that have been studied extensively: Lactobacillus G.G. which is a strain of Lactobacillus-- casei organism that has been shown in many different studies in children to be effective. That is the kind of probiotic you want to give to children, particularly if you're worried about daycare infections and so forth. This is the take-home message: All the probiotics don't function the same and you need to have clinical evidence to support that.

Now what's happening is there's an explosion in the research community around how commensal bacteria which are health-promoting bacteria in the intestine function. And as we find out new things like I pointed out to you in studies we've done with necrotizing colitis, we're going to be able to come up with new ways of treating disease or preventing disease in the appropriate fashion. So that is very important.

The other thing -- and I don't want to dwell on this because it's a whole topic in and of itself -- there's evidence that suggests that genes could be placed into probiotics, probiotics given to an individual and it delivers a specific molecule that's very helpful in the treatment or prevention of disease. There's a study showing that an anti-inflammatory human molecule given to a probiotic can reduce the inflammation. That's a whole new area. We'll probably have another session like this a few years down the road to discuss what's happening. But that's the sort of way where things are headed in the context of probiotics.

QUESTION:

Okay. I had a question on supplements in terms of the shelf-life and the potency of the product, some are refrigerated, I've seen that. And, I mean, how can you tell when these products are no longer...

DR. MARY ELLEN SANDERS:

You can't. That is the bottom line. I mean, a consumer has no way of knowing. So you really have to go with a company that you trust. So the other hint is to make sure that the products are labeled with counts at the end of shelf-life. So some products, as I mentioned, especially dietary supplement products will say "contains one billion per capsule at the time of manufacture". Well, that to me says that they probably don't have very good stability, and that this organism is going to die over time.

And many of these dietary supplements are on the market have a two-year shelf-life. I mean, they're on the market for a long time. That is why you really have to buy from a company that you trust. A company that has something to lose if somebody finds out that they're labeling a product containing something that in fact is not in the product.

QUESTION:

Just a tag on to that too, method of delivery of the product. There are things, you're talking about encapsulated, you know, probiotics versus not. Can you tell me what's what?

DR. MARY ELLEN SANDERS:

A lot of times, especially with supplement companies, they want a gimmick. They want something that differentiates them from the fray. And so they'll talk about enteric coating, they'll talk about having better shelf-life, whatever. And at the end of the day, I think the question has to be: is this product as manufactured known to cause a health benefit in people? Whether it's enteric coated or not, whether it's in a yogurt versus a pill.

And I know that that's a tough answer to your question because you want to be able to have something really quick. You know, a check box or a quality seal that you could just say, "I know this works." But that's not how the industry is based right now.

DR. ALAN WALKER:

What are the bases for an organism being labeled as probiotic-Is it given a sufficient quantity that it may be partially broken down in the stomach, in the intestine, but it gets into the colon you can demonstrate it exists there. If it isn't shown to be cultured in the intestine, then it's probably not fulfilling the role of a probiotic. That's why Mary Ellen dwelled on the ten to the eighth, ten to the twelfth, the number of organisms you need.

The other thing is some of the dietary supplements are manufactures like drugs are so that they don't get broken down in the stomach, they're acid resistant and get into the intestine. And then to come back to your comment, probiotics given in food usually are more protected because the food itself neutralizes all these things like acid and so forth going down in the intestine.

ELAINE MCGEE:

And with her question with the dairy, when a probiotic is in dairy, if it's a reputable company, you should go by the sell by date

DR. MARY ELLEN SANDERS:

Right.

ELAINE MCGEE:

The ideal amount of probiotic.

DR. ALAN WALKER:

The problem is the FDA doesn't go and look at all these products and make sure that dose exists at the shelf-life time. You have to take it on faith. And that's why, again, taking a company that has a lot of pride in providing what they say is well worth doing.

QUESTION:

And then regarding that shelf-life scenario, if you store it improperly, like, right, even driving home in a hot car maybe, might that will ruin it?

DR. MARY ELLEN SANDERS:

Certainly temperature is one factor that is important to the survival of probiotics. And high temperature these organisms, especially the lactobacillus and bifidobacterium are sensitive to very high temperatures. And so, yes, if you're in a car and it goes to 110 degrees because it's in the direct sun, that could cause some of these microbes to die. Would you agree, Miguel?

MIGUEL:

Yes.

QUESTION:

Will cooking with them?

DR. MARY ELLEN SANDERS:

Oh, yeah. Well, that's out. There is a cheese on the market right now that has probiotics, but don't make grilled cheese sandwiches with it.

ELAINE MCGEE:

Well, speaking of products though, looking into the future, where do you see probiotics? What other types of food products do you see probiotics coming out into? Besides dairy

DR. ALAN WALKER:

From my perspective, I see studies showing its specific effect. One recommends a specific probiotic for a specific issue. Again, I come back to daycare centers. There are specific organisms used in these studies. And what one should probably do is recommend that for the individuals. Some of the general probiotics are a little bit like taking multivitamins.

DR. MARY ELLEN SANDERS:

Yeah.

DR. ALAN WALKER:

They just kinda have a generalized effect. But if you're looking for specific prevention, let's say traveler's diarrhea. Going off to a developing country and you don't want to get a bug, you can take the organisms that have been studied in that regard and shown to be effective.

QUESTION:

What is the name of the particular strain that you said that kids should take if they're in daycare?

DR. ALAN WALKER:

Well, I was talking about Lactobacillus G.G. which is Lactobacillus casei. And G.G. is named after the two individuals who isolated it from the human intestine.

DR. ALAN WALKER:

And it's been studied extensively in Finland and they did a lot of clinical studies. The other organism is a bifidobacterium BB12 which comes from Denmark. Again, they've done a lot of studies with that in pediatric population.

For example, again, I have multiple connections so I don't wanna push Danone, but Danone was able to acquire the rights to LGG and they have this product called Danimals which is the sort of thing one wants to give babies of mothers who have been delivered by Caesarian section and so forth.-because there are proven studies with that organism for a specific condition. Okay? There are all sorts of information I think we need to make your public aware of when they make a decision.

ELAINE MCGEE:

And a lot of the strain information is in that wonderful table that's in your packet.

QUESTION:

What happens to probiotics during the course of antibiotics? Is it advisable to tell people to take a probiotic product while they are on antibiotics or should they only start after?

DR. ALAN WALKER:

No, that's what's usually recommended.

Most probiotics survive the use of an antibiotic. And essentially what it does, when you take an antibiotic, you disrupt the balance. I talked about that. And so what happens is this helps bring the balance back in favor of enough health promoting bacteria to help prevent the diarrhea that occurs with antibiotics.

QUESTION:

You had mentioned taking probiotics for people with the hospital acquired infection. I worked with two people last week on a study on seeing if one woman's mother, like, in her 90s was dead within a year with recurrent diarrhea. And then another patient that has been dealing with the problem and with diarrhea for three years with C-difficile, and I'm just wondering how well known is this as a treatment that can be used to help mitigate the diarrhea problem?

DR. ALAN WALKER:

Your point is extremely well taken. I think in some ways, the public is better informed about probiotics than is the physician. One of our goals as we try to promote probiotics is to make the public aware of this. There are some very good studies that have shown that if a probiotic, and they use Sacrimises villardi (PH) principally but also L.G.G. is given after you treat for the clostridial infection.

You can't cure the infection with probiotics because it's too tough to do that. So you use an antibiotic and instead of stopping and then let 'em get a recurrence, you start 'em on the probiotic. And very often they don't get recurrence. And usually with an elderly person, that means a hospitalization. That's means a huge expense to our health care system. So these are ways of preventing them.

DR. MARY ELLEN SANDERS:

I'd also like to add there was a paper published in 2007 in the *British Medical Journal* done in England where they actually looked at a product, which is called Actimel in England, but it's called DanActive in the US. And they looked at hospitalized elderly, and by elderly I think it was over 50.

DR. ALAN WALKER:

A relative term.

DR. MARY ELLEN SANDERS:

Right. The subjects were 50 and older, hospitalized for other purposes. And it was a blinded controlled study where half the group took the DanActive product, and the other half was given a placebo product. And the group that got the DanActive product actually had a lower incidence of antibiotic-associated diarrhea. I'm sorry, these patients were on antibiotics.

And also, there was a lower incidence of *C. difficile* isolated from the diarrhea that was there. And so, you know, there's an example of the food product that you potentially just added to your diet, or the diet of someone who might be a potential candidate or struggling with this that may make a difference.

DR. ALAN WALKER:

You know, we're in a health care crises. You all know this. Because our expenses are greater than our ability to pay. So as a result, more and more people are being uninsured. Well, some of the causes of these increased expenses is that someone comes in the hospital for X problem, while in the hospital, they pick up an infection that's going around the hospital.

So instead of staying in three days, they stay in seven days. And that adds up. There's a study done in Warsaw, where every baby coming into a hospital is given a probiotic. And they looked at the secondary infections, not the primary reason they're in the hospital. And almost invariably, they left the hospital sooner than those who didn't. Japan is now embarking on automatically putting every baby that comes in the hospital on a probiotic yogurt to see if they can do the same thing. And that's a study that's ongoing. So there's lots of ways that the use of probiotics can be very helpful both in general and specifically, certain medical conditions.

ELAINE MCGEE:

Sounds like it's a stay-tuned. So much more to come.

ELAINE MCGEE:

Any final questions real quick?

QUESTION:

Quick question. When a breast-feeding mom is consuming probiotics, what compounds are transmitted through the breast milk?

DR. ALAN WALKER:

Again, that's a very, very good question. I just had a Scandinavian fellow for three years from the group that did all these allergy studies. And we looked at that. What happens is that when a mother is nursing and is taking a probiotic, there's a substance called TGF Beta, it's an anti-inflammatory substance that exists in breast milk, but is enormously bumped up. That's the same molecule that's been attributed to producing less auto-immune disease, less allergy. So they think that's what's probably going on.

QUESTION:

Thank you.

ELAINE MCGEE:

I just wanted to say a few things. Thank you so much for spending your morning with all of us. I hope you learned something new. I know I did. I wanted to let you know, if some questions come up as you're writing your stories and what have you, their e-mails are in the packet, and they're kindly offering, you know, to respond to anybody.

And if anything else comes up, Beth Heller's with Edelman, her contact information's in the packet. And they're also available for like 25 minutes or so now in case there's anything that you want to ask us too. Thanks so much for spending the morning.

* * *END OF AUDIO* * *

* * *END OF TRANSCRIPT* * *

EDELMAN PUBLIC RELATIONS: "DANNON WALDORF SESSION"

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