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CENTER FOR SCIENCE IN THE PUBLIC INTEREST



# **CHANGERS** 5 studies that made a difference

Quick & Easy Breakfasts PROBIOTICS No sure bet Misleading Ads & Labels



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# TAKING "BIG FOOD" TO COURT



t's a simple ask. Consumers should be able to easily identify whether foods marketed to them are healthy or not. But they often can't. Restaurants and

grocery store aisles are awash in deceptive

claims, making it difficult for us to know the truth about what we eat.

The Center for Science in the Public Interest, Nutrition Action's publisher, is fighting back against these marketing scams, under the leadership of Maia Kats, our director of liti-

gation. We use the law as a tool ... and it's a powerful one.

In fact, CSPI has pioneered the use of litigation to remedy deceptive food marketing.

Over the years, our lawyers have forced more accurate labeling from many of the biggest companies, including Campbell, Coca-Cola,

uten Free

**Cheerios Protein or Cheerios Sweetened?** 

General Mills, and PepsiCo. These victories have deterred other manufacturers from making similarly deceptive claims.

A few examples:

photo:

■ Naked Juice. Naked's Kale Blazer can "pack more kale into your diet," promised ads a few years ago. But Kale Blazer is largely comprised of orange and apple juices. Another Naked juice, Green Machine, has more apple juice than any of its greens.

Last year, we reached an agreement with Naked, a unit of PepsiCo. Among the changes: images of fruits and vegetables on Naked labels now reflect how much of those ingredients are inside the bottles.

CVS Algal-900 DHA. "Clinically shown to improve memory," claimed CVS's omega-3

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supplement. But the claim was based on a study that does "not reveal any improvement in working memory," according to the Federal Trade Commission. Our lawsuit, filed in 2016, is still in progress.

Cheerios Protein. General Mills marketed Cheerios Protein as a protein-enriched version of original Cheerios, charged our 2015 lawsuit. Yet Cheerios Protein has just a smidge more protein...and about 16 times the sugar.

In July, we reached a settlement with General Mills. The front of the box will now say "Sweetened" loud and clear, and "7g protein," not "11g protein with milk."

> Jamba Juice. "Whole fruit! That's how we blend." claims the company.

In fact, many of Jamba's smoothies are made with juice blends that contain mostly (cheap) pear, apple, or grape juices. They're not predominantly whole fruit or vegetables.

What's more.

a large Jamba "fruit" smoothie can have as many as 600 calories and 128 grams of total sugars (about 30 teaspoons' worth).

In August, we filed a lawsuit charging that the company is misleading customers. As we went to press, there was no word on a resolution.

We're far from done. As long as the food industry keeps trying to trick consumers, CSPI will keep putting companies on notice that we won't let them get away with deceptive ads and labels. Stay tuned.

Peter G. Lurie, MD, MPH, President Center for Science in the Public Interest

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#### BY BONNIE LIEBMAN

F aulty. Flawed. Messy. Untrustworthy. The science behind most experts' advice on diet and health is a popular target these days (thanks, in part, to the food industry). One frequent attack: The advice is based on weak "observational" studies that can't prove cause and effect. Wrong and wrong. Those types of studies are not necessarily weak, and most advice is also based on randomized clinical trials, the gold standard of scientific research. Here are five game changers.

#### The DASH Studies

The first DASH (Dietary Approaches to Stop Hypertension) study was published in 1997.<sup>1</sup>

And it's still the bedrock of today's advice from the American Heart Association, American College of Cardiology, American Cancer Society, and others: Eat a diet rich in fruits and vegetables, include low-fat dairy, poultry, fish, beans, whole grains, oils, and nuts, and limit sweets, sugarsweetened beverages, and red meats.<sup>2</sup>

How did DASH happen?

"The study started with observations of populations where there's very little high blood pressure and very little rise in blood pressure with age," says co-author Frank Sacks, professor of cardiovascular disease prevention at the Harvard T.H. Chan School of Public Health.

In contrast, roughly one out of two U.S. adults now have high blood pressure, or hypertension. It's a major risk factor for strokes and heart attacks.

"Also, studies on vegetarians suggested that diet plays a large role in blood pressure," says Sacks.

"So scientists at NHLBI—the National Heart, Lung, and Blood Institute—decided that we needed a definitive clinical trial to see whether the DASH dietary pattern would lower blood pressure." (For more on clinical trials, see "What Kind of Study?" p. 5.)

The trial randomly assigned 459 adults —most had higher-than-normal blood pressure—to eat one of three diets:

a typical American diet,

a typical American diet with extra fruits and vegetables (instead of snacks and sweets), or a DASH diet (a typical American diet with extra fruits, vegetables, and low-fat dairy and less saturated fat and cholesterol).

The researchers prepared all the food for the participants. (That's part of what made the study "well controlled.")

"After eight weeks, the fruits and vegetables had lowered blood pressure significantly" compared to the typical American diet, says Sacks, "but only about half as much as the DASH diet lowered pressure."

Why?

"Even now, we don't fully understand how those changes—switching from high-fat to low-fat dairy, from beef and pork to fish and chicken, and from butter to oils—lowered blood pressure more than fruits and vegetables alone," says Sacks.

The next study: DASH-Sodium. Since all three diets in the DASH study had the same amount of sodium, "the NHLBI scientists thought we should see what happens if you reduce sodium in both the DASH diet and the typical American diet," Sacks explains.

So researchers randomly assigned 412 people to eat one of those two diets with high levels of sodium (3,300 milligrams a day), with intermediate levels (2,400 mg a day), or with low levels (1,500 mg a day).<sup>3</sup>

"The blood pressure reduction from cutting salt was substantial, especially in older people," says Sacks. And if you add the drop from switching to a DASH diet, the difference was huge.

"The DASH diet alone can lower blood pressure as much as taking a blood-pressure-

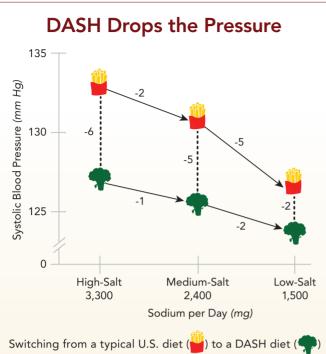
# **DASH in a Nutshell**

Here's a hybrid of the two best versions of the DASH diet. It has a "wild card" that lets you eat one extra serving of carbs, protein, or healthy fat each day.

The diet is low in saturated fat, added sugar, and salt, and rich in potassium, magnesium, calcium, and fiber.

Note: The servings are *small*. If you eat more than about 2,000 calories a day, make them larger. Daily Servings

	<b>Vegetables &amp; Fruit</b> <b>1 SERVING:</b> ½ cup (or 1 cup greens) or 1 piece fruit	11
	<b>Grains</b> 1 SERVING: ½ cup pasta or rice or cereal or 1 slice bread	4
E	<b>Low-fat Dairy</b> 1 SERVING: 1 cup milk or yogurt or 1½ oz. cheese	2
	<b>Legumes &amp; Nuts</b> 1 SERVING: ½ cup beans or ¼ cup nuts or 4 oz. tofu	2
	Poultry, Fish, Lean Meat 1 SERVING: ¼ lb. cooked	1
	Oils & Fats 1 SERVING: 1 Tbs.	2
0	Desserts & Sweets 1 SERVING: 1 tsp. sugar or 1 small cookie	2
	Wild Card Poultry, Fish, Lean Meat or Oils & Fats or Grains or Desserts & Sweets	1



cuts blood pressure by an average of 6 points. Pressure drops 1 more point if you switch to a medium-salt diet and another 2 points if you eat a low-salt diet.

Source: Adapted from <u>N. Engl. J. Med. 344: 3, 2001</u>.

lowering drug," says Sacks. "If you also cut salt, it can be superior to drug treatment."

But the researchers had yet another question.

"We wondered what would happen if you took away some of the carbs in DASH and replaced them with unsaturated fats or protein," says Sacks. (More than half of the extra protein would come from plant foods like beans and nuts.)

That led to a third DASH study, known as OmniHeart. $^{\underline{4}}$ 

"Replacing some of the carbohydrate with protein or unsaturated fat lowered blood pressure, cholesterol, and triglycerides more than the original DASH diet," says Sacks.

(See "DASH in a Nutshell," p. 3, for a hybrid of the higher-protein and higherunsaturated-fat diets.)

"But bear in mind that it wasn't just a diet in which everything was slathered with cheese or oil," notes Sacks.

"It was the same healthy DASH dietary pattern."

#### 2 The Sat Fat Trials

How do we know that saturated fats raise and unsaturated fats lower—LDL ("bad") cholesterol, a major risk factor for heart disease?

Early observational studies like the Seven Countries Study reported higher rates of heart disease in people who ate more sat fat.

"But what really made an impression were two parallel series of trials testing which fats raised or lowered blood cholesterol," says Martijn Katan, a cardiovascular

disease expert and emeritus professor of nutrition at Vrije Universiteit in Amsterdam.<sup>56</sup>

"By 1965 at the latest, it was beyond

a reasonable doubt that if you replace saturated fats with polyunsaturated fats, you get a substantial lowering of total cholesterol," says Katan.

Then, in the early 1970s, researchers started to look at LDL cholesterol separately. By 2016, a World Health Organization



It's one of the best-established medical facts: Lowering your LDL ("bad") cholesterol cuts your risk of a heart attack. How to do it? Replace bad fats (red meat, cheese, butter, coconut oil, fatty sweets, etc.) with good fats (oil, salad dressing, mayo, nuts, fish, avocado, etc.).

Source: Adapted from "The Facts on Fat," American Heart Association.

report had looked at 91 trials.<sup>Z</sup> "There wasn't one single fat prevents heart attacks and strokes," says Sacks.

And is there any reason to think that lowering LDL might *not* protect the heart?

"Absolutely not," says Katan. "The effect of LDL on heart disease risk is one of the best established facts in the whole of medical science."

The data testing statins or other drugs that slash LDL is massive.

"The latest summary included 27 trials involving 174,000 patients," says Katan.<sup>8</sup> "That's a staggering number."

But there's even more evidence that lower LDL means less heart disease.

"There's a whole bunch of genetic variants that raise or lower LDL, and they all raise or lower coronary risk," says Katan.

"So the evidence is coming from all directions, and there's really no way to explain it all, except by assuming that lowering LDL lowers the risk of coronary heart disease."

And it's not just the cholesterol trials. Several randomized clinical trials from the 1950s, '60s, and '70s looked not just at LDL but also at heart attacks and strokes.<sup>9</sup>

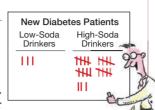
"If you look at the four highest-quality trials together, they provide direct evidence that replacing a diet high in saturated fat with a diet high in polyunsaturated

# What Kind of Study?

Here's a quick primer on the two types of studies on diet and health you're likely to hear about, and a few of their pros and cons.

#### **OBSERVATIONAL STUDIES**

Most are "prospective cohort" studies that ask thousands of people what they typically eat, then wait five or 10 years to see who gets heart disease, diabetes, cancer, etc. The best studies filter



out the impact of smoking, exercise, and other potential **«** "confounders"—that is, something else about the participants or what they do that accounts for the results.

**Pro:** You can see a decade's-long impact on health. **Con:** You can't tell if unknown confounders explain the results.

#### RANDOMIZED CLINICAL TRIALS

Researchers randomly assign people to eat one of two (or more) diets. The best studies provide all the food. After a few months, the scientists see if the diets made a difference in a risk factor (like blood pressure). If trials want to look at diseases like diabetes, cancer, or heart disease, they typically have to enroll thousands, wait for years, and rely on participants to choose their own food.

Pro: If the study finds a difference in a disease or risk factor, you can be sure the diet caused it.Con: If a diet has no effect, it's possible that people didn't stick to it, or that the trial was too short or too small.

# **R** The Diabetes Prevention Program (DPP)

One out of three adults now have prediabetes. Nine out of ten of them don't know it.

"The good news is that if you have prediabetes, the CDC-led National Diabetes Prevention Program can help you make lifestyle changes to prevent or delay type 2 diabetes and other serious health problems," says the <u>Centers for Disease</u> <u>Control and Prevention</u>.

"Through the program, you can lower your risk of developing type 2 diabetes by as much as 58 percent (71 percent if you're over age 60)."

Those results come from the Diabetes Prevention Program (DPP), a trial that randomly assigned 3,234 people with prediabetes to take a placebo or metformin ries," says DPP researcher Judith Wylie-Rosett, who heads the division

of health promotion and nutrition research at the Albert Einstein College of Medicine in New

(a drug that lowers

blood sugar), or to a

The lifestyle goals:

"lifestyle" group.

lose excess weight

and exercise for at

"The DPP partic-

ipants counted the

ate because it was

counting calo-

easier for them

to calculate than

grams of fat they

least 2½ hours a

week.

York. After nearly three years, the average lifestyle participant had lost only 12 pounds, and only 58 percent had met the exercise goal.

Yet that was enough to slash the risk of diabetes by 58 percent, far more than metformin, which trimmed risk by 31 percent.<sup>10</sup>

"And people in the lifestyle group still had a 27 percent lower risk of diabetes than the placebo group 15 years later, even though many had regained the lost weight," says Wylie-Rosett.<sup>11</sup>

Researchers are still tracking the participants' risk of diabetes, along with their risk of cancer and memory loss.

"It's truly amazing to me that we've gone from doing a trial to having a lifestyle program that's reimbursed by Medicare," says Wylie-Rosett.

"How often does that happen?"

# The DRINK Study

Do sugary drinks make people gain weight? The DRINK trial answered that question in 2012.

Researchers randomly assigned 641 mostly normal-weight Dutch children who usually drank sugary beverages to get a daily 8 oz. drink sweetened with either sugar (104 calories) or artificial sweeteners (0 calories) at school each day. Neither the children nor the investigators knew who got which drinks.<sup>12</sup>

"The question was whether the children who got zero calories would sense the difference and compensate by eating more calories from some other source," says Katan. "Would those kids come home and say, 'Mom, I'm hungry. I want a snack,' or would they just have their usual lunch and dinner?"

The result: After 1½ years, the average child who got the sugary drinks had gained roughly two pounds more than



Hemoglobin A1C, a long-term measure of blood sugar, is the easiest way to test for diabetes.

Source: Adapted from <u>cdc.gov/diabetes/library/</u> socialmedia/infographics.html. the average child who got the sugarfree drinks. And the chubbier kids gained about three pounds more if they got their usual sugary drinks.<sup>13</sup>

"Even the thinnest children were not immune to the effect of sugary drinks," says Katan. "But heavier kids may be less likely to sense when they're eating fewer calories and when they're overeating."

More evidence that some people are more vulnerable than others: an observational study published on the same day as the DRINK trial that tracked roughly 11,000 nurses and health professionals for 12 to 18 years.

Among men and women with a genetic risk of obesity, those who drank at least one sugary drink a day were four times more likely to become obese than those who drank less than one sugary drink a month.14

"Sugary drinks make you fat. They circumvent your innate mechanisms for keeping your body weight stable," says Katan.

"If you eat beans or whole wheat bread, they're not fattening because you feel full, so you don't eat other things."

In contrast, "if you drink sugary drinks, including fruit juices-there's no difference between fruit juices and soda-they will simply slip in through the back door and you'll just keep eating as much as you usually do. "They're bur-



It's not just soda but also sports drinks, lemonade, iced tea, and juices that can lead to weight gain.

that question. But it was one of the largest.<sup>15</sup>

"We enrolled over 800 people so we could compare the effect of diets higher or lower in carbohydrate, fat, or protein," says Harvard's Frank Sacks.

Pounds Lost was also one of the longest diet trials.

"We did a two-year study, which was quite unusual at the time, because body weight reaches a low point after about six months in a weight-loss program and then you have weight regain," says Sacks.

Participants got daily meal plans and went to individual and group sessions

ed low-carb versus low-fat dietshave had similar results

The most recent: DIETFITS randomly assigned 609 people to cut as much fat or carbs as possible from their diets, rather than count calories.

After one year, each group had lost roughly the same weightabout 12 pounds.<sup>16</sup> And that's no surprise, since both groups ended up cutting a similar number of calories-about 500 to 600 a day, on average. (See "If the Diet Fits," May 2018, p. 11.)

"We expected people with insulin resistance to do better on a low-carb diet, but they didn't," says lead investigator Christopher Gardner, professor of medicine at the Stanford University School of Medicine. (People with insulin resistance have an increased risk of diabetes.)

Maybe that's because both diets were healthy.

"Nobody was supposed to eat added sugars or refined grains, and everybody was supposed to eat vegetables," says Gardner. "Americans get a quarter of their calories from added sugars and refined

grains and a woefully low number of calories from vegetables...if you don't count potatoes.

"If we could just get people to make those changes," says Gardner, "we'd be well on our way."

<sup>1</sup> N. Engl. J. Med. 336:

- 1117, 1997
- J. Am. Coll. Cardiol. 63: 2960, 2014.
- <sup>3</sup> N. Engl. J. Med. 344:
- <u>3, 2001</u>.
- 4 JAMA 294: 2455, 2005 <sup>5</sup> Metabolism 14: 747,
- 759, 766, 776, 1965 <sup>6</sup> Am. J. Clin. Nutr. 17:
- 281, 1965.
- <sup>7</sup> who.int/nutrition/publications/nutrientrequirements/ sfa\_systematic\_review/en.
- Lancet 385: 1397, 2015.
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- 15 N. Engl. J. Med. 360: 859, 2009.
- 16 JAMA 319: 667, 2018.

Pounds Lost

When you're trying to lose weight, what matters more: cutting fat, cutting protein, or cutting carbs?

Pounds Lost-which began in 2004wasn't the first or the last study to explore



The healthy low-fat chicken dinner (left) has whole grains and beans. The healthy low-carb dinner uses those calories for extra fat in the salmon, nuts, and avocado.

where they learned what to eat. Each of the diets cut about 750 calories a day.

"We came up with a very simple but somewhat unexpected result," says Sacks. "The composition of fat, carbohydrate, and protein in a healthy diet had no effect whatsoever on weight loss or regain." Nor did it affect hunger.

Most other studies-they typically test-

# Quick Studies

A snapshot of the latest research on diet, exercise, and more

# **Colorectal Cancer & Weight**



Diagnoses and death rates for colorectal cancer have dropped by more than 45 percent since the 1980s, in part because of early screening in people aged 50 or older. The question is: Why are rates rising in people aged 20 to 49? Researchers tracked roughly 85,000 women aged 25 to 42 for

14 years. Each 11-pound weight gain after age 18 was linked to a 9 percent higher risk of colorectal cancer. Women with obesity had nearly twice the risk of those whose weight was in the lower half of the "healthy" range.

What to do: Lose (or don't gain) extra pounds. Although this kind of study can't prove that excess weight caused the higher risk of colorectal cancer in these younger women, increasing weight is a well-established risk factor in older people. Others include type 2 diabetes, too little exercise, and diets high in red and processed meats.

JAMA Oncol. 2018. doi:10.1001/jamaoncol.2018.4280.

# Exercise & Parkinson's Disease

ould staying active lower your risk of Parkinson's disease?

Researchers looked at eight studies that tracked more than 544,000 adults for six to 22 years. Men who reported doing the most physical activity had a 32 percent lower risk of Parkinson's than those who did the least. There was no clear link in women.



What to do: Although this study can't prove that exercise prevents Parkinson's, it's one more reason to keep moving.

JAMA Network Open 2018. doi:10.1001/jamanetworkopen.2018.2421.





C an drinking more fluids help prevent recurring urinary tract infections (UTIs)? Until recently, no one had looked.

So scientists at Danone Research—Danone sells bottled water—randomly assigned 140 premenopausal women to drink either an extra 1½ liters (about 6 cups) of water a day or no more water than usual. (All the women had been diagnosed with at least three UTIs in the previous year and all typically drank less than 1½ liters of fluids a day before the study started.)

Over the following year, those assigned to drink no extra water averaged 3.2 UTIs. Those who drank extra water averaged only 1.7 UTIs.

What to do: Getting UTIs? Aim for about 12 cups of water or other unsweetened fluids a day. Fewer UTIs won't just help *you*. Roughly 15 percent of antibiotics used by humans are prescribed to treat UTIs. Fewer UTIs lowers the risk that bacteria become resistant to the drugs.

JAMA Intern. Med. 2018. doi:10.1001/jamainternmed.2018.4204.



# **Do Organic Foods Protect Against Cancer?**

C an eating organic foods lower your risk of cancer? French researchers tracked nearly 69,000 adults for five years.

Those who reported eating the most organic foods were 76 percent less likely to be diagnosed with lymphoma and 34 percent

less likely to be diagnosed with postmenopausal breast cancer than those who ate the least.

What to do: Eat a diet rich in fruits and vegetables—organic or not. It's worth buying organic foods to protect the environment, but it's too early to know if they prevent cancer.

Something else about people who buy organic food could explain their lower risk. And although it's likely that the organic-food eaters were exposed to fewer pesticides, this study had no data to prove it.

JAMA Intern. Med. 2018. doi:10.1001/jamainternmed.2018.4357, doi:10.1001/jamainternmed.2018.4363.

# 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.



## 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.

#### Do Probiotics Work?

#### 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 interchangeable—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



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

# More Harm than Good?

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.<sup>1</sup>

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.



In one study, the gut microbiome took *longer* to recover from antibiotics when people took a probiotic.

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.<sup>2</sup>

"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 transwhich 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* 

<sup>1</sup> <u>Benef. Microbes 8: 507, 2017</u>. <sup>2</sup> <u>Cell 174: 1406, 2018</u>.

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 wellcharacterized.

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* <u>reduces the risk</u> 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. diff*-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 <u>study</u> 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 <u>study</u> 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

plantation," 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, 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 antibioticresistant 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-

# Most-Promising Probiotics

Nearly all probiotics need more evidence. These strains have the best so far, according to our latest look (see Jul./Aug. 2017, p. 8).



In two studies, 170 women taking antibiotics for bacterial vaginosis (BV) also took a placebo or Lactobacillus rhamnosus GR-1 and Lactobacillus reuteri RC-14 daily. After a month, BV had cleared up in roughly 90 percent of the probiotic takers versus 40 or 50 percent of the placebo takers.<sup>1,2</sup>

In 21 studies that enrolled nearly 4,800 children and adults, the yeast Saccharomyces boulardii cut the risk of antibiotic-associated diarrhea in half.<sup>3</sup>





In two studies of roughly 440 adults with irritable bowel syndrome, Bifidobacterium infantis 35624 eased symptoms like abdominal pain and distension more than a placebo.4,5

-Caitlin Dow

<sup>1</sup> Microbes Infect. 8: 1450, 2006. <sup>2</sup> Can. J. Microbiol. 55: 133, 2009. <sup>3</sup> Aliment. Pharmacol. Ther. 42: 793, 2015. 4 Gastroenterol. 128: 541, 2005. <sup>5</sup> Am. J. Gastroenterol. 101: 1581, 2006

> 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.

# The Healthy Cook

# Go with the grain



#### BY KATE SHERWOOD

Whole grains play a starring role in these two sides. Have precooked grains? Each dish comes together in just 15 minutes.

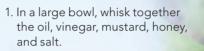
Got a question or suggestion? Write to Kate at <u>healthycook@cspinet.org</u>

SERVES 4

# Wheat Berry & Apple Salad

- 2 Tbs. extra-virgin olive oil
- 1 Tbs. cider vinegar
- 2 tsp. whole-grain mustard
- 1/2 tsp. honey
- 1/4 tsp. kosher salt
- 1 apple (any type), cored and diced
- 8 cups salad greens
- 1 cup cooked wheat berries
- 1/4 cup chopped toasted walnuts

PER SERVING (2 cups): calories 230 | total fat 12 g | sat fat 1.5 g | carbs 27 g fiber 6 g | total sugar 6 g | added sugar 1 g | protein 6 g | sodium 200 mg



2. Toss with the apple, salad greens, wheat berries, and walnuts.

# Wild Rice & Mushrooms



- 2 Tbs. extra-virgin olive oil
- ½ lb. mushrooms (any type), sliced
- 3 sprigs fresh thyme
- 4 scallions, sliced
- 2 stalks celery, thinly sliced
- 2 cups cooked wild rice blend
- 1⁄4 tsp. kosher salt
- In a large non-stick pan, heat the oil over medium heat until shimmering hot. Sauté the mushrooms with the thyme, stirring occasionally, until browned, 5-7 minutes. Discard the thyme stems.
- Stir in the scallions, celery, and rice. Cook while stirring until hot, about 1 minute. Season with the salt.

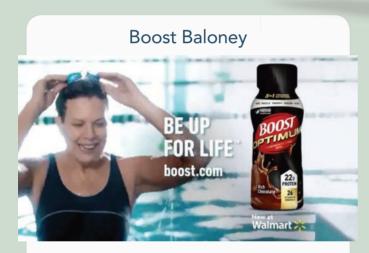
PER SERVING (¾ cup): calories 220 | total fat 8 g | sat fat 1 g | carbs 33 g fiber 3 g | total sugar 2 g | added sugar 0 g | protein 5 g | sodium 150 mg

# **Tricks** of the **Trade**

BY LINDSAY MOYER & BONNIE LIEBMAN

Do food company execs sit around all day dreaming up ways to make us think we need something —snack bars, sports drinks, "nutritional drinks," whatever—that we could do without? Or trying to convince us that products have *more* of something—fruit, vegetables, you-name-it—than they do? There's a sucker born every minute, they say. And these companies are out to prove it.

Jolene Mafnas compiled the information for this article.



"To keep up this pace, I drink **Boost Optimum**," says the fit woman in the <u>TV ad</u>.

"Boost Optimum, with 5 in 1 advanced nutrition, helps support muscle, energy, bone, normal immune function, and vision," adds the authoritative voice-over.

"Support" should set off your "huh??" meter. It's code for "a claim that needs little evidence." (Ditto for "maintains" and "enhances.")

For example, Boost Optimum has "antioxidants, including vitamin C and selenium, to help support normal immune function," says the label. But there's no good evidence that lack of vitamin C or selenium causes immune problems in Americans.

And it has "vitamin A, zinc and riboflavin to help support normal vision." But few Americans have vision problems caused by too little of those nutrients.

As long as you can eat real food, you don't need a bottle of milk protein concentrate, soy protein isolate, sugar, oil, vitamins, and minerals. Nestlé, a leading infant formula maker, is just trying to *boost* its market.



Milking It

"Every 8-ounce glass has 5 grams of added prebiotic fiber, 50% more calcium than dairy milk, and 2 grams of sugar," says the carton of **Silk Prebiotics Almond & Cashew with Oats**.

"What are prebiotics?" the label asks. "Beneficial fiber that helps feed the good bacteria in your gut."

Translation: Silk adds chicory root extract (inulin), a carbohydrate that your digestive enzymes can't completely break down. That means it ends

up as lunch for the bacteria in your gut.

Does that matter for your health? It's not clear.

The FDA has only decided that inulin has one health benefit: increasing calcium absorption. But since each cup of Silk has 45 percent of a day's calcium, you're already getting a large dose. Given the (still-uncertain) evidence that excess calcium may promote prostate cancer, that's a downside for some men.

At this point, only two things are clear: inulin often causes gas...and is always a good marketing tool.



# That's Breakfast?

"Now More Fruit!" boast boxes of Kashi Ripe Strawberry Soft Baked Breakfast Bars.

Judging by the ingredients list, Kashi's definition of "ripe strawberry" is "pear juice concentrate, tapioca syrup, cane

sugar, apple powder, strawberry

puree concentrate, cornstarch, vegetable glycerin, natural flavor, and elderberry juice concentrate for color."

We guess "Now More Sweetened Juice Concentrate Goo!" wouldn't sound nearly as enticing.

#### Processed One Bar



"Your stomach's being rude and it's screaming for food," says the <u>TV ad</u>. "Here comes the 90-10-1 crew with the **Protein One** bar for you!"

Protein One bars have 90 calories, 10 grams of protein ("to help you feel full," the website says), and 1 gram of sugar, "for all your snack emergencies."

It's not clear that protein makes you feel more full than other nutrients (see Sept. 2018, p. 3). And who needs a snack made of (gas-producing) chicory root extract, whey and soy protein isolates, maltitol, palm kernel oil, glycerin, and a dozen other processed ingredients?

Apple, anyone?

### VeryLittleBerry Cheerios



"Flavored with Real Fruit," says the front of the **Very Berry Cheerios** box. "Berries and breakfast go together like cereal and milk," says the back.

Yes, but these very berry Cheerios aren't...umm...very berry. They've got no whole berries and more *salt* (and sugar) than any berry powder...and a serving has no more than <sup>1</sup>/<sub>17</sub> teaspoon of salt.

Cheerios is big on "real." Its "limited edition" **Pumpkin Spice Cheerios** were "made with REAL pumpkin puree." Again, they had more salt (and sugar) than pumpkin.

"Real food tastes better," said in-store signs for Cheerios. It sure does.

# Nature's Powder



"Experts say to eat a lot of fruits and veggies," says the <u>TV ad</u> for **One A Day with Nature's Medley**. "But are you getting enough of their nutrients?" Nature's Medley is "the only complete multivitamin with antioxidants from one total serving of fruits and veggies."

Talk about a switcheroo! Experts say to eat a lot of fruits and vegetables, *not* their nutrients or their antioxidants.

A two-gummy serving (so much for "one a day") has 100 *milligrams* of powders from onion, pomegranate, blueberry, broccoli, etc. That's about what <sup>1</sup>/<sub>40</sub> teaspoon of sugar weighs.

Surely, One A Day isn't trying to convince people that taking its gummies is as good as eating a "total serving" of fruits and vegetables. Nah.

#### Sorta Scamwater



"I'm the sorta-fit spokesguy for **Vitaminwater Active**, the drink that gives you the sports-level hydration you need to get in a good workout," says the <u>ad's</u> ordinary, non-athlete at the gym.

Wait. Why would you need "sports-level hydration" if you're not doing sports (for hours)? You don't.

Each bottle of Vitaminwater Active has 100 calories' worth of mostly sugar, plus a smattering of vitamins you can do without.

It's just Vitaminwater's (that is, Coca-Cola's) attempt to convince ordinary people that they can't just drink ordinary water after an ordinary workout.

Why swallow half a day's added sugar just to boost Coke's bottom line?

### Burreakfast, Anyone?



"Expect more from breakfast," say **Sweet Earth Breakfast Burritos**. Got that right.

The six burrito varieties are stuffed with enough tofu or eggs plus beans, peas, seasoned seitan (wheat protein), and/or "benevolent" (veggie) bacon to reach 10 to 20 grams of protein apiece. Not bad for 200 to 360 calories.

Our favorites: the zesty **Lighten Up!** (tofu, spinach, salsa, black-eyed peas, peppers) and the meaty-tasting **Protein Lover's** (eggs, quinoa, cheese, veggie bacon and "grounds").

Most come in wraps that are at least half whole-grain. (We didn't find any 100-percent whole-grain breakfast burritos.) And none top 4 grams of saturated fat—1 gram for the cheese-less flavors—or 500 milligrams of sodium.

Tip: Some of Sweet Earth's claims go too far. A case in point: if you need to "defog your morning brain," don't rely on a "functional breakfast burrito" called **Get Focused!** 

# 

# McMuffin Makeover

Need a quick breakfast sandwich that doesn't involve a drive-thru?

**Good Food Made Simple** makes it, ahem, *simple* to pull off without so much as cracking an egg or washing a skillet.

The company's perfectly sized frozen **Egg White Patties** (with 6 grams of protein each) go from microwave to toasted whole-wheat English

muffin in 80 seconds flat. (A large egg has 6 grams of protein.)

With a mere 35 calories and 140 milligrams of sodium per patty, there's room to toss on some avocado or a thin slice of cheese. Or, if you can spare another 30 seconds, add a handful of baby spinach or a few slices of ripe tomato.

Tip: Want to toss your entire heat-and-eat breakfast sammie into the microwave, bread and all? Try frozen **Evol Lean & Fit Egg White, Kale, Roasted Tomato & Goat Cheese**. (Its "multi-grain" flatbread isn't all whole grain, but at least it's more than half.) Instead of microwaving it inside its package, wrap it in a paper towel and put it on a plate to lower the odds that any chemicals in the package end up in your food.

# Plan B BREAKFASTS

Thinking outside the cereal box

Y LINDSAY MOYER & JENNIFER URBAN

### Near-Perfect Pancakes



"Inspired by the heirloom flapjack recipes that sustained frontiersmen and women, we perfected this recipe for modern tastes and needs," says Kodiak Cakes about its Flapjack & Waffle Mix.

No kidding. For starters, Kodiak's mixes are 100% whole grain. That's a find.

And they're foolproof. Just add one cup of water to one

cup of mix. That makes two 200-calorie servings of about three 4-inch pancakes each. You can choose from:

■ Frontier Cakes. With just a teaspoon of total sugar per serving, the Whole Wheat Oat & Honey and the Buttermilk & Honey are subtly sweet.

■ Power Cakes. Kodiak adds wheat protein isolate and whey and milk protein concentrates to boost the protein from 8 grams per serving (in the Frontier Cakes) to 14 grams (in the Power Cakes). The **Buttermilk** have just half a teaspoon of sugar. Most flavors, like the fabulous **Dark Chocolate**, hover around 2 teaspoons, so

they're plenty sweet without syrup.

■ Energy Cakes. Energy, shmenergy. You'll get energy—that is, calories—from *any* of Kodiak's cakes. So ignore the added "B-vitamins for a natural source of clean energy" and "superfood ingredients" claims for the Pumpkin Flax and Buttermilk & Chia, and just enjoy them.



There's nothing wrong with a low-sugar wholegrain cereal for breakfast. Or oatmeal. Or yogurt and fruit. But sometimes you want a break from the routine, whether you fancy something savory (eggs, a sandwich, a burrito) or sweet (pancakes, waffles). A few companies have made those staples healthier and more convenient. Here's a look.

Bonus: Most of these items can wait patiently in the freezer, pantry, or fridge until you're ready to change up your a.m. meal.

Jolene Mafnas helped compile the information for this article.

# Superior Sausage

LANKY

Morning

Want to enjoy sausage without worrying that processed meats have been linked to cancer?

Or without fretting over the fatty pork in a typical breakfast sausage like Jimmy Dean Original, which squeezes 140 calories and 4½ grams of saturated fat into a paltry 1.2 oz. patty.

Then go meatless. Mouthwater-

ing MorningStar Farms Original and Maple Flavored Veggie Sausage Patties taste darn close to the real thing...with no sat fat. Each 1.3 oz. patty hovers around 80 calories, 8 grams of protein (from wheat, soy, and egg whites), and 250 milligrams of sodium.

Our tasters' runner-up: Field Roast Apple Maple Breakfast Sausage wheat-protein links.

## Easy Eggs

A vegetable-packed egg scramble, frittata, or omelet makes a fine breakfast that's free of refined flour.

But for your heart's sake, it's best to stick to no more than four or five yolks a week (see June 2015, p. 11).

What's an egg-a-day eater to do? Pick up a refrigerated carton like **All Whites** or **Egg Beaters 100% Egg Whites**, and sidestep the egg-cracking entirely.

Tip: Go heavy on the veggies and light on the cheese. Try your egg whites with chopped broccoli, scallions, and a sprinkle of sharp cheddar. Or bell pepper, mushroom, and onion. Or tomato, spinach, and freshly grated parmesan. Mmm.



# **Bowled Over**



"Each ingredient matters," say Healthy Choice's four Power Bowls. "Our recipes provide the right combination of ingredients such as whole grains, mixed greens, vegetables and egg whites to fuel your day."

They're being modest. Many Power Bowl ingredients break new ground in the freezer case:

■ Whole grains. The base of each bowl is a nutty mix of steel cut oats, farro, buckwheat, and quinoa.

■ Beans. Beans for breakfast? Believe it. The Pesto & Egg White Scramble is mixed with white beans, while the Unwrapped Burrito Scramble goes with black.

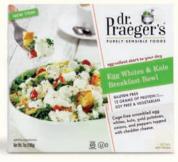
■ Vegetables. Healthy Choice tosses in tomatoes plus a smattering of dark greens (chard, kale, and spinach).

Thanks to those impressive ingredients, you get 3 to 5 grams of unprocessed, intact fiber and 10 to 15 grams of protein, all for no more than 200 calories and  $1\frac{1}{2}$  grams of saturated fat (there's little or no cheese).

The sodium—which ranges from 430 milligrams in the Pesto

& Egg White Scramble to 600 mg in the Turkey Sausage & Egg White Scramble beats many bowls.

Another good bet: **Dr. Praeger's**. Two out of its three **Breakfast Bowls**—the **Egg Whites & Kale** (our favorite) and the **Huevos Rancheros** sport numbers and ingredients like Healthy Choice's.



Time to give your cereal bowl the day off.

# Winning Waffles

Kellogg's Eggo Nutri-Grain toaster waffles are "made with 8g whole grain." True, but they have more white flour than whole wheat.



L'Eggo of 'em. Today, it's easier than ever to get wholegrain waffles in the freezer case. Try Kashi. Or Good Food Made Simple. Or Kodiak Cakes Power Waffles.

And who needs syrup? Try yours with nut butter and bananas, buttery spread and berries, or yogurt and fruit.

# RIGHT STUFF

# Squash Made Simple



Sweet and satisfying, nutrient-rich and perfect for roasting, winter squashes like acorn, butternut, Hubbard,

spaghetti, and pumpkin—are irresistible...except for their thick skin. Sometimes, peeling or carving it away is one step too many.

Enter **delicata squash**. Its thin skin is so, well, delicate, that it will melt in your mouth.

Just cut a delicata in half lengthwise and scoop out the seeds. Then brush with olive oil and place cut side down (or slice into inch-thick half moons and toss with olive oil) and roast in a 450°F oven until soft, about 30 minutes. Or try our Dish of the Month.

Serve as a side, or toss the half moons into your salad. Mmm. It's a less-sweetthan-butternut crowd pleaser.

Like any winter squash, delicatas are no slouch in the nutrient department. You can count on a good dose of fiber, vitamin A (from carotenoids), lutein, potassium, and folate, all for around 80 calories per cup.

And delicatas are smaller than some winter squashes, so they're perfect for a dinner for one or two.

To find a riper—that is, sweeter—delicata, look for orange, not greenish, stripes on the pale yellow skin. But don't delay. They disappear from most supermarkets by spring.

In other words, carpe diem those delicatas.

quick tip

# FOOD PORN

# That Takes the Cake

Like most restaurants, **TGI Fridays** serves plenty of 1,000-calorie appetizers and entrées. So naturally, customers are going home *famished* unless they order dessert.

Not to worry. Fridays' **Red Velvet Sparkler Cake** to the rescue.



It's "a three-tiered red velvet cake that's a Friday night celebration in itself, layered with cream cheese frosting then topped with whipped cream and candy sprinkles," says the chain.

The cake is "served alongside a scoop of vanilla ice cream" and strawberry fizz candy clusters. The "sparklers" are Strawberry Pocky—that is, sugar-and-oil-cov-



Fridays' celebration packs 1,690 calories and more than two days' worth of saturated fat (43 grams), plus 35 teaspoons of sugar (nearly all of it added).

It's like eating six Twinkies smothered in an entire (14 oz.) container of Häagen-Dazs strawberry ice cream. Nothing like a dense brick of cake—our piece weighed in at ¾ *pound*—to make your meal memorable!

Remember when dessert was *just* a piece of cake? Now it's three layers, plus frosting, whipped cream, ice cream, candy sprinkles, candy clusters, and candy sticks.

Thanks, Fridays. Can't wait to celebrate!

TGIFridays.com (800) 374-3297

#### A sharp knife is a safe knife because it's less likely to slip while cutting. No sharpener? Some kitchen or hardware stores will sharpen your (non-serrated) blade for a few bucks.

DIS

of the month

**Roasted Delicata** 

Cut 2 seeded delicata squash

into half moons. Toss with a thin-

ly sliced red onion and 2 Tbs.

olive oil. Roast on a rimmed

sheet pan at 450°F for 30 min-

utes. Top with 1⁄4 cup toasted

pumpkin seeds. Serves 4.