

FDA 101: Dietary Supplements

 [fda.gov/consumers/consumer-updates/fda-101-dietary-supplements](https://www.fda.gov/consumers/consumer-updates/fda-101-dietary-supplements)

Office of the Commissioner

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Dietary supplements can help improve health but can also have risks. Get the facts on supplements and how the FDA regulates them to help keep you safe.



[Español](#)

Multivitamins, vitamin D, echinacea, and fish oil are among the many dietary supplements lining store shelves or available online. Perhaps you already take a supplement or are thinking about using one. Dietary supplements can be beneficial to your health, but they can also involve health risks. So, it's important that you talk with a health care professional to help you decide if a supplement is right for you.

Read on to learn what dietary supplements are, are not, what role the U.S. Food and Drug Administration has in regulating them, and how to make sure you and your family use supplements safely.

What Are Dietary Supplements?

Dietary supplements are intended to add to or supplement the diet and are different from conventional food. Generally, to the extent a product is intended to treat, diagnose, cure, or prevent diseases, it is a drug, even if it is labeled as a dietary supplement. Supplements are ingested and come in many forms, including tablets, capsules, soft gels, gel caps, powders, bars, gummies, and liquids.

Common supplements include:

- Vitamins: such as multivitamins or individual vitamins like vitamin D and biotin
- Minerals: such as calcium, magnesium, and iron
- Botanicals or herbs: such as echinacea and ginger
- Botanical compounds: such as caffeine and curcumin
- Amino acids: such as tryptophan and glutamine
- Live microbials: commonly referred to as “probiotics”

What Are the Benefits of Dietary Supplements?

Dietary supplements can help you improve or maintain your overall health, and supplements can also help you meet your daily requirements of essential nutrients.

For example, calcium and vitamin D can help build strong bones, and fiber can help to maintain bowel regularity. While the benefits of some supplements are well established, other supplements need more study. Also, keep in mind that supplements should not take the place of the variety of foods that are important for a healthy diet.

What Are the Risks of Dietary Supplements?

Before buying or taking a dietary supplement, talk with a health care professional—such as your doctor, nurse, registered dietitian, or pharmacist—about the benefits and risks.

Many supplements contain ingredients that can have strong effects in the body. Additionally, some supplements can interact with medications, interfere with lab tests, or have dangerous effects during surgery. Your health care professional can help you decide what supplement, if any, is right for you.

When taking dietary supplements, be alert to the possibility of a bad reaction or side effect, also known as an adverse event.

Problems can occur especially if you:

- Combine supplements
- [Mix medicines and supplements](#)
- Take too much of some supplements
- Take supplements instead of medications

If you experience an adverse event while taking a dietary supplement, immediately stop using the supplement, seek medical care or advice, and [report the adverse event to the FDA](#).

How Are Dietary Supplements Regulated?

The Law

The Federal Food, Drug, and Cosmetic Act was amended in 1994 by the Dietary Supplement Health and Education Act, often referred to as DSHEA, which defined “dietary supplement” and set out the FDA’s authority regarding such products. Under existing law:

- The FDA does NOT have the authority to approve dietary supplements for safety and effectiveness, or to approve their labeling, before the supplements are sold to the public.
- Under the FD&C Act, it is the responsibility of dietary supplement companies to ensure their products meet the safety standards for dietary supplements and are not otherwise in violation of the law.
- Dietary supplement labels are required to have nutrition information in the form of a Supplement Facts label that includes the serving size, the number of servings per container, a listing of all dietary ingredients in the product, and the amount per serving of those ingredients. They also must have a statement on the front of the product identifying it as a “dietary supplement” or similar descriptive term, e.g., “herbal supplement” or “calcium supplement”.

In general, even if a product is labeled as a dietary supplement, a product intended to treat, prevent, cure, or alleviate the symptoms of a disease is a drug, and subject to all requirements that apply to drugs.

The FDA’s Role and Actions to Help Keep You Safe

Even though the FDA does not approve dietary supplements, there are roles for the agency in regulating them.

- Since companies can often introduce a dietary supplement to the market without notifying the FDA, the agency's role in regulating supplements primarily begins after the product enters the marketplace.

- The FDA periodically inspects dietary supplement manufacturing facilities to verify companies are meeting applicable manufacturing and labeling requirements.
- The FDA also reviews product labels and other labeling information, including websites, to ensure products are appropriately labeled and that they do not include claims that may render the products drugs, e.g., claims to treat, diagnose, cure, or prevent diseases.
- The FDA monitors adverse event reports submitted by dietary supplement companies, health care professionals, and consumers as well as other product complaints for valuable information about the safety of products once they are on the market.
- If a product is found to be unsafe or doesn't otherwise comply with the law, the FDA can:
 - Work with the company to bring the product into compliance.
 - Ask the company to voluntarily recall the product.
 - Take action to remove a dangerous product from the market.

Tips to Be a Safe and Informed Consumer

Before taking a dietary supplement, talk with your health care professional. They can help you decide which supplements, if any, are right for you. You can also contact the manufacturer for information about the product.

- Take only as described on the label. Some ingredients and products can be harmful when consumed in high amounts, when taken for a long time, or when used in combination with certain drugs or foods.
- Do not substitute a dietary supplement for a prescription medicine or for the variety of foods important to a healthy diet.
- Do not assume that the term "natural" to describe a product ensures that it is safe.
- Be wary of hype. Sound health advice is generally based upon research over time, not a single study.
- Learn to spot false claims. If something sounds too good to be true, it probably is.

Why Is It Important to Report an Adverse Event?

If you experience adverse event, also known as a side effect or bad reaction, the FDA encourages both you and your health care professional to report the adverse event to the FDA.

You can help the FDA, yourself, and other consumers by reporting an adverse event. A single adverse event report can help us identify a potentially dangerous product and possibly remove it from the market.

For a list of potential serious reactions to watch for, and to learn how to report an adverse event, please see the FDA's webpage, [How to Report a Problem with Dietary Supplements](#).

Adverse events can also be reported to the product's manufacturer or distributor through the address or phone number listed on the product's label. Dietary supplement firms are required to report serious adverse events they receive about their dietary supplements to the FDA within 15 days.

As a part of [FDA modernization efforts for field operations](#), all of our Centers now directly receive reports of problems or adverse reactions with [FDA-regulated products](#). Please direct concerns to the appropriate FDA center by visiting our [SmartHub webpage](#), which will guide you to the appropriate webform or phone number.

If you are not able to use the SmartHub, you may also call 1-888-INFO-FDA and follow the prompts to report a problem. If you require the use of a Relay Service, please call the Federal Relay Services at 800-877-8339. This is a toll-free relay service to call federal agencies from TTY devices.

NOTE: The ORA consumer complaint coordinator telephone numbers previously available are no longer in use.

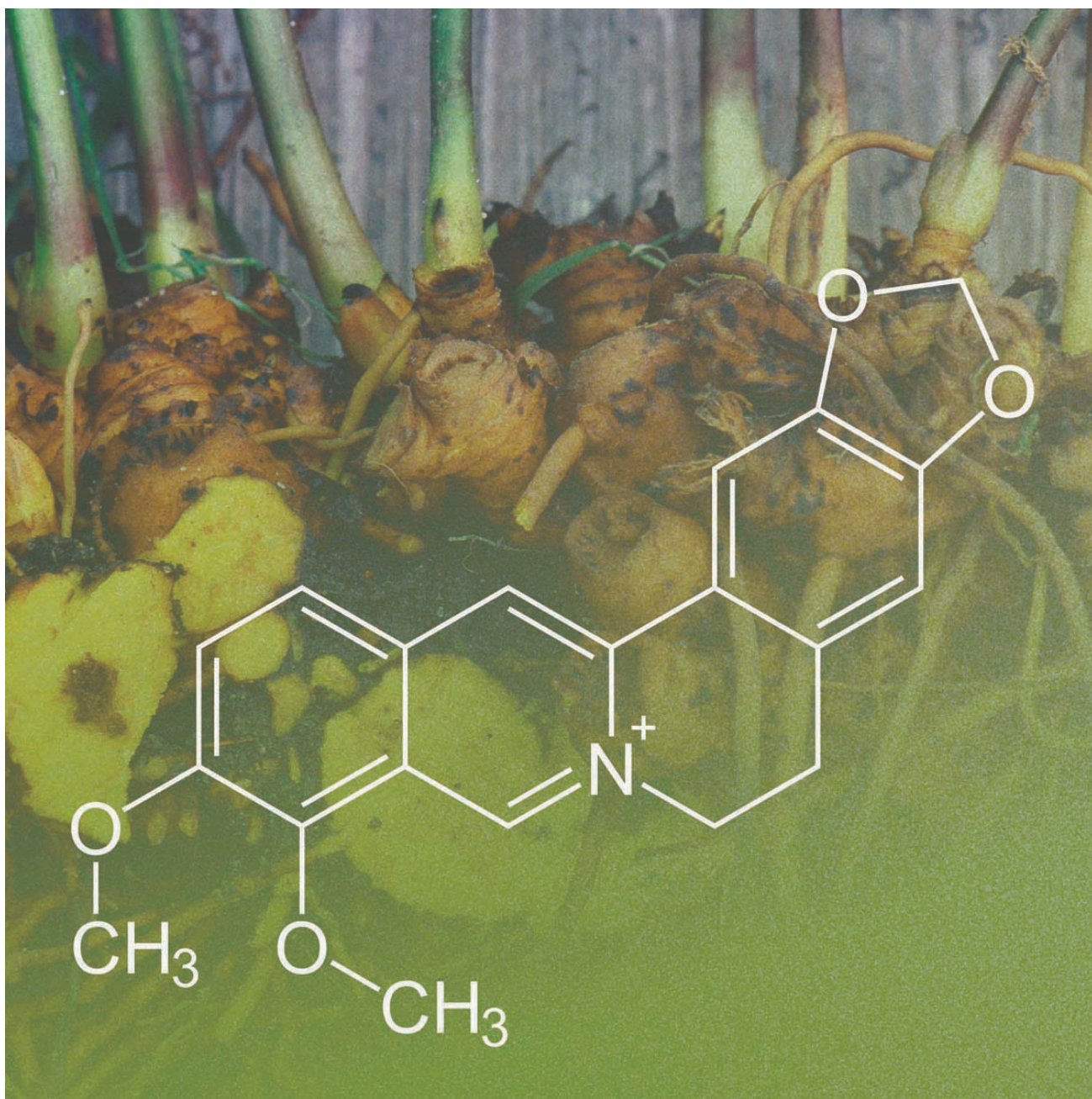
Additional Resources:

- [Dietary Supplements](#), FDA
- [Information for Consumers on Using Dietary Supplements](#), FDA
- [Dietary Supplement Fact Sheets](#), National Institutes of Health

In the News: Berberine



nccih.nih.gov/health/in-the-news-berberine



Berberine is a compound found in some plants such as European barberry, [goldenseal](#), goldthread, Oregon grape, phellodendron, and tree turmeric. Plants containing berberine have been used medicinally for thousands of years in Ayurvedic medicine and traditional Chinese medicine. In Ayurvedic medicine, plants rich in berberine have been used for treating infections, for promoting wound healing, and as a remedy for gastrointestinal disorders.

Traditionally, berberine has also been used as a treatment against various bacteria, fungi, and viruses. Today, berberine is often sold as an herbal dietary supplement and is promoted as a remedy for diabetes, high cholesterol levels, high blood pressure, and canker sores, and most recently as a weight loss aid.

Recently, berberine has gained popularity across the internet and on social media platforms such as TikTok for its purported ability to induce weight loss. However, while some preliminary studies have suggested that berberine may play a role in losing weight, there haven't been many clinical trials (studies conducted in people), so there isn't enough rigorous scientific evidence to determine whether it is effective.

There is some evidence that berberine may have a modest effect on lowering blood glucose levels in people with type 2 diabetes and may reduce cholesterol levels. Berberine may have additional beneficial effects on high blood pressure when used in combination with the medication amlodipine.

In general, when taken orally, berberine is well tolerated; however, it is not without its risks and side effects. The most common adverse effects of berberine include abdominal pain, constipation, diarrhea, nausea, and vomiting. People who are pregnant or breastfeeding should not use berberine, and it should not be given to infants. Berberine can cause or worsen jaundice in newborn infants and could lead to a life-threatening problem called kernicterus. Berberine might also interact with medicines in negative ways.

Additional Resources

- [Berberine \(MedlinePlus\)](#)
- [Weight Control](#)
- [Natural Doesn't Necessarily Mean Safer, or Better](#)

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Why berberine, a trendy diet supplement, isn't 'nature's Ozempic.'

 [washingtonpost.com/wellness/2023/06/20/berberine-weight-loss-natures-ozempic](https://www.washingtonpost.com/wellness/2023/06/20/berberine-weight-loss-natures-ozempic)

Katie Camero

June 20, 2023



Savannah Crosby had been gaining weight despite tracking her calories and hitting the gym. Looking for answers, the 34-year-old Texas resident fell down an internet rabbit hole that led her to berberine: a yellow, bitter-tasting chemical found in plants that some claim helps weight loss.

TikTok's Berberine Fad Is About More Than 'Nature's Ozempic'

 [wired.com/story/berberine-social-media-trend](https://www.wired.com/story/berberine-social-media-trend)

Kate Knibbs

July 31, 2023

Berberine went viral as a weight loss wonder pill. Its success on social media shows how broken the supplement industry is.



Photograph: Mariya Borisova/Getty Images

The claims are enticing. “Helps decrease belly fat.” “Improves ovulation.” “Prevents recurring UTIs.” “Reduces inflammation levels.” “Lowers cholesterol.” “Improves depression.”

These splashy promises don’t appear on the side of a bottle, a billboard, or a TV commercial. Instead, they come from social media posts from regular people gushing about their new favorite dietary supplement: a chemical called berberine. They’ve nicknamed the product “nature’s Ozempic,” a play on the popular type 2 diabetes drug that became [a phenomenon](#) when it was discovered to cause weight loss. One prominent berberine booster on TikTok calls it “natures ozempyyy” and swears that it has reduced his food cravings. The popularity of these videos has translated into a major surge in sales this summer. Thorne, a supplement company selling the product, told WIRED that its berberine sales have increased more than 165 percent in the second quarter of 2023 so far, compared to sales in the same time period last year.

Berberine isn’t new. It’s been an ingredient in traditional Chinese and Ayurvedic medicine for centuries, and can be found in a variety of plants, including barberry, a shrub with tart berries, and goldenseal, a perennial herb with a thick, knotty root. But as the Ozempic craze took off, berberine’s devotees began talking it up as a kind of kinder, gentler alternative to prescription medications. Now, Western wellness types, who take it a la carte in pill form, evangelize for it enthusiastically. “I can’t think of another example where something has gone viral to this extent,” says Craig Hopp, a deputy division director at the National Center for Complementary and Integrative Health, the National Institutes of Health office tasked with researching alternative medicines.

Featured Video

[Bill Nye Answers Science Questions From Twitter - Part 4](#)

Amid all this hoopla, one specific claim about berberine got my attention. I saw it over and over: “Lowers blood sugar.” It was as if the algorithms knew precisely what would push me over the edge to actually purchase the stuff. I developed gestational diabetes a few years ago; to keep my blood sugar in check, I followed a carb-restricted diet and went through my pregnancy staring longingly at bagels and pricking my finger three times a day. It sucked. Now, with an increased chance of developing [type 2 diabetes](#), I’ll do just about anything to avoid it. After a few consecutive nights getting served these giddy pro-berberine videos, I ordered two different kinds of berberine capsules online. What was the harm? It was natural, after all.

They arrived on my doorstep the next day. One bottle contained 200-milligram capsules of berberine, while the second contained pills with berberine and cinnamon, divided into 2,000-

milligram capsules. The first option touted “GI support” and “immune support.” The second highlighted its gluten-free, “non-GMO” formulation.

Shaking the pills out onto my palm, it was impossible to tell which was which—they were both translucent, oblong, and filled with a yellow powder that resembles turmeric. Yet despite their identical appearances, they were very different dosages. I had no idea which one to take.

Instead of swallowing either pill, I called Cassandra Quave, a doctor and research scientist who studies medicinal plants, to ask whether berberine was even wise to take at all.

Her response? “It’s crazy to me that these things are available.”

When people criticize alternative medicine, it’s often for being new-fangled snake oil. But some alternative medicines sold as supplements are worth scrutinizing not because they’re ineffective but because they’re so *potent*. A supplement like berberine can be as beneficial as a pharmaceutical, but also as strong as one. Yet, culturally, people often view supplements as benign additions to their diets, rather than remedies that can be both effective and intense.

Quave is wary of the easy availability of single-ingredient supplements like berberine, which are sold in powerful compound form with few warnings about potential side effects, and without the same regulatory scrutiny as over-the-counter or prescription medications. She finds the fad for casually taking berberine to lose weight troubling for several reasons. “Berberine is a natural antibiotic, so it interferes with the growth of different bacteria in the intestines,” she says. “This is not something you’re supposed to take on on a long-term basis, because you are changing the dynamics of your gut microflora.” Plus, berberine is known to interfere with enzymes in the body that break down other drugs, so it can cause dangerous interactions.

Berberine has [antibiotic properties](#), as Quave noted, which is why it is often used to treat bacterial diarrhea on a short-term basis. Studies also suggest that it can [indeed reduce](#) insulin resistance. It is a remarkable substance, and it’s easy to understand why people are excited about its benefits. But that does not mean it’s wise to start ingesting this powerful pharmacological compound as casually as a cough drop. And even alternative healthcare practitioners have concerns.

“It does get a little scary to me when we’re talking about extracts of particular herbs, because that gets to be as strong as a pharmaceutical medication,” Jaquelyn Taylor, an herbalist in Chicago, says. “I’d worry about antibiotic resistance with using berberine.” Taylor does not instruct her clients to take berberine to lower blood sugar or for weight loss. When she does incorporate herbs containing berberine into a recipe, she pairs them with other herbs that will help temper its effects, following traditional methods.

Lisa Makeeva, an Ontario-based dietician who often treats digestive disorders, has recommended berberine to some of her patients for years. Makeeva has even made TikTok videos about berberine's effects—but she has reservations about how the supplement has turned into a fad diet product. “I think any supplement you're introducing should be monitored by a health care practitioner,” she says; when her clients start on it, Makeeva orders blood work to watch how and if it impacts their blood sugar. She does not recommend it for shedding body mass. Despite TikTok claims about berberine's weight-loss benefits, its functionality as a dieting aid hasn't actually been proven in peer-reviewed studies.

“We don't really have much data to show that taking berberine will lead to weight loss,” she says.

Although they are sometimes embraced as alternatives to modern medicine, botanical ingredients are an undeniably vital component of mainstream pharmacology. Aspirin comes from willow bark; metformin, the diabetes medicine to which berberine is often compared, is derived from a plant known as French lilac. If a plant-derived substance is classified by the US Food and Drug Administration as a pharmaceutical drug, it must undergo rigorous testing before it's approved.

But if a plant-derived substance is classified as a supplement, rigor goes out the window. There's no mandatory development and approval process for supplements. In 1994, the Dietary Supplement Health and Education Act (DSHEA) changed how the FDA could regulate supplements, undermining its power within a rapidly-growing market. While the FDA evaluates medications for safety and efficacy before they go to market, the agency only has the power to ban a supplement after it has been sold and there is evidence it is harmful. (To understand more about this dynamic, read this [investigation](#) WIRED published in 2020 into why the memory supplement PrevaGen stayed on the market despite questions about its safety.)

Despite several high-profile public health disasters related to supplements, including the herbal stimulant ephedra causing a wave of heart attacks and other adverse effects, regulatory control over the supplement industry remains startlingly lax—even as the market has exploded in popularity. According to Patricia Deuster, acting executive director at the Uniformed Services University's Consortium for Health and Military Performance and chair of the Department of Defense's Dietary Supplement Subcommittee, there were only around 3,000 dietary supplements on the market when DSHEA became law. Today, there are between 80,000 and 150,000. Some of these supplements are demonstrably safe and beneficial, like Vitamin D. But many of them are not.

This explosion in popularity has not led to a commensurate spike in rigorous research. “The biggest problem with dietary supplements is that there really isn't much funding to do

randomized controlled trials,” Deuster says. “It’s usually funded by the supplement company if it’s done at all, so that the opportunity for good evidence is almost nonexistent.”

This laissez-faire regulatory atmosphere has led to a wide variety of products that simply don’t do what they say they’re going to do—or much of anything at all. It has also led to cases like berberine, where the danger isn’t that the supplement will be ineffective so much as it is that people taking it aren’t made aware of how powerful it can be in ways they weren’t expecting. They may think they’re taking a gentle, all-natural weight-loss remedy with lots of traditional uses; instead, what they are taking is a powerful antimicrobial that may interfere with other medications, isolated and sold in a pill form that resembles traditional preparations only as much as a caffeine pill resembles a guarana leaf.

Although it hasn’t been subject to the same trials that a pharmaceutical goes through during its approval process, and although berberine is not regulated like a medication, it can still function like one. The body doesn’t know or care, after all, how a substance is classified. “There’s no difference between a pharmaceutical drug and the sort of compounds like berberine that are sold in supplements. They’re exactly the same,” says Pieter Cohen, an associate professor of medicine at Harvard Medical School who studies supplements. “The law creates these artificial categories.”

Some supplement companies do make efforts to at least offer some educational materials for their customers. For example, when I asked Thorne whether it is putting out any messaging about how powerful berberine is, and how it may not be suitable for long-term use, a spokesperson told me that the company had run a Q&A with an in-house doctor via Instagram Stories. (It is now [available](#) to rewatch if you sit through an earlier Q&A about an unrelated supplement in the Highlights tab.) The most easy-to-find information about berberine on the company’s Instagram account is a Reel promoting the ingredient as “a supplement you don’t want to miss.” In addition to GI support, the promotion hails berberine for its “weight-management” properties. There’s nothing about side effects or about its suitability for long-term use, nor is there anything to that effect on the bottle itself—just a warning not to use while pregnant. (If you navigate to Thorne’s website, the company does offer a warning not to use while pregnant there, too, in addition to a warning about potential allergies and drug interactions.)

Some supplements have origins that are startlingly medical; melatonin, for example, is widely viewed as a mild sleep aid. While it is generally safe, melatonin is a potent hormone, originally extracted from a cow’s pineal gland, and it can have a number of adverse effects and drug interactions, ranging from nausea to increased blood pressure. When its bovine origins raised concerns that it could become contaminated with mad cow disease, manufacturers largely shifted over to deriving the hormone synthetically. In his illuminating 2006 book *Natural*

Causes: Death, Lies, and Politics in America's Vitamin and Herbal Supplement Industry, journalist Dan Hurley points out how odd it is that this kind of product is widely considered something less serious than medication. "One has to wonder how a synthetic brain hormone ever wound up being sold as a 'dietary supplement' in the first place," Hurley writes.

The way metformin and berberine are treated makes this false dichotomy obvious. In addition to getting called "nature's Ozempic," berberine is also frequently discussed as "nature's metformin." But metformin is already nature's metformin. The primary difference, then, isn't that metformin is unnatural while berberine is natural, or that one works and one doesn't. It is that metformin has been evaluated within a far more stringent system, and obtaining it requires a prescription, whereas berberine is subject to far less scrutiny and is available to order online with no medical oversight or third-party quality control checking the purity of the ingredients.

"Herbal supplements can be especially dodgy when it comes to issues with contamination," says Nicholas Milazzo, the lead researcher at nutrition and supplement database Examine.com. The industry has an alarming track record regarding unlisted and sometimes hazardous ingredients turning up in supplements.

Although many people turn to supplements out of a desire to avoid Big Pharma, the quality control problems within the industry mean that they may end up inadvertently consuming prescription medications anyways. An [analysis](#) of 800 over-the-counter dietary supplements sold between 2007 and 2016 found more than one pharmaceutical ingredient in 20 percent of the products, ranging from antidepressants to anabolic steroids—and the FDA [doesn't have the authority](#) to recall these kinds of tainted supplements.

This spring, for example, Illinois-based supplement company NOW [discovered](#) that counterfeiters were selling fake versions of its products on Amazon; the counterfeit supplements contained a pharmaceutical drug called sildenafil. If that name isn't familiar to you, it's likely because sildenafil is the generic name for a very popular brand-name drug: Viagra.

Berberine isn't a new supplement, but it is an intensely timely one. It's a fad because people are enthralled by Ozempic and eager to find a "natural" alternative. Without the breakthrough in semaglutide drugs, it might've remained just another obscure herb somebody's acupuncturist recommended. "Because it's riding that anti-pharma wave, it doesn't surprise me that berberine has taken off," says Derek Beres, a writer and podcaster who covers the intersection of wellness culture and conspiratorial thinking. Berberine's boosters gave it an unbeatable marketing hook by positioning it in opposition to Ozempic, the pharmaceutical industry's most recent blockbuster drug.

Above all, it's a fad because of how desiccated trust in public health is. Alternative medicine has been popular for decades, but in recent years, it has moved from the fringes into an increasingly mainstream and [politically extreme](#) position. Wellness communities are drifting politically rightward and define themselves in opposition to the medical establishment.

Berberine's rise did not happen in a vacuum. Its popularity is emblematic of a rising worldview, one championed by Democratic presidential primary contender Robert F. Kennedy Jr., which rejects evidence-based medicine in favor of contrarian pseudoscience. It's no coincidence that some major players [pushing berberine](#) include figures like Joseph Mercola, an osteopath whose immensely popular alternative-health websites push [anti-vaccine conspiracy theories](#).

Supplements are the self-help aisle—pulling yourself up by your bootstraps, living your best life—made manifest in pills and powders. Why wait for some old fogey in a white coat to fix your body, when you could simply purchase elixirs yourself? While medications are prescribed by an elite medical authority figure, supplements are peddled by entrepreneurs beholden only to the market.

And social platforms, especially TikTok, are making it easier than ever for anyone to take on the role of supplement peddlers. The industry had already used multilevel marketing schemes to rope regular people into shilling herbs for decades—Herbalife, which launched in 1980, [remains](#) one of the largest MLMs in the world—but influencer culture has accelerated this blurring of lines between customer and seller.

"I started seeing it blow up on Instagram and TikTok, being compared to 'nature's Ozempic,'" says Shelby Worth, a bubbly, earnest nursing assistant based in Prince Edward Island, Canada. "That's when I decided to give it a try."

Worth is not a stereotypical wellness influencer. She doesn't do fancy matching workout sets or use a ring light. She mostly posts tossed-off videos of herself wearing sweatshirts in her kitchen, often goofing around with her fiancé. But she's interested in leading a healthy lifestyle and was curious enough about berberine to order her own. When Worth posted her own series of videos detailing her experience with the remedy, she racked up millions of views. She even nabbed a sponsorship deal from a supplement company after her initial video on berberine went viral on TikTok; it's her first brand partnership. Afterward, she was approached by two companies about trying Ozempic and posting about the experience; she declined, eager to continue her focus on alternatives to prescriptions.

Worth's quick jump from new customer to active seller demonstrates how quickly regular people can get pulled into the sprawling supplements industry. Even though I ended up

throwing my berberine out, in the course of reporting this story, new videos hawking the product continued to appear in my feeds daily.

“Order berberine,” Worth’s TikTok bio now reads, linking potential customers out to her affiliates.

Updated 7-31-23, 11:10 am EDT: This story was updated to correct Thorne's berberine sales figures.